PHD

Internal hip fracture fixation systems: analysis of implant performance for the optimisation of test protocols

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INTERNAL HIP FRACTURE FIXATION SYSTEMS:
ANALYSIS OF IMPLANT PERFORMANCE FOR THE OPTIMISATION OF TEST PROTOCOLS.

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SUMMARY

The sliding hip screw is widely regarded as the optimum treatment for intertrochanteric fractures of the femur, allowing impaction of the bone fragments to create a bony support across the fracture site. A wide range of these devices are available commercially with a variety of success rates. This study was undertaken to evaluate the performance of two contrasting designs, the Dynamic Hip Screw (Synthes), a lateral plate system, and the Gamma Locking Nail (Howmedica), an intramedullary design.

An initial cadaveric study was undertaken to establish the failure modes and corresponding loads for the two implants, under static loading conditions. The failure modes for the two implants included shaft fractures, lag screw bending and predominantly cut-out of the lag screw from the femoral head. The load transfer between the implants and the bone was analysed on a strain gauged composite femoral model under the same loading conditions.

A biomechanical investigation was then undertaken to determine the performance of the two devices under conditions of dynamic loading. This was to establish the optimum conditions for lag screw sliding, hence the minimum risk of lag screw cut-out. The loads required for lag screw sliding were found to be lowest under conditions of increased angles of dynamic flexion, with a fast load application rate. A randomised clinical study was undertaken to compile clinical data on the performance of the implants. From a sample of cases, the maximum axial forces acting on the implants were calculated and found to be less than those required within the biomechanical study. A synchronised biomechanical study was finally undertaken to more accurately recreate the clinical loading conditions.

From the accumulation of knowledge derived from the complete range of tests, a test protocol was developed that would appropriately test any sliding implant, prior to clinical testing.

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INTRODUCTION

1.1 The Problem of Proximal Femoral Fractures

Fractures of the proximal femur, commonly referred to as hip fractures, are becoming an increasing problem throughout the world due to improved standards of living and health care, resulting in an increase in the average life span of the population. In 1990 around 1.66 million hip fractures occurred worldwide, 50% of which were in Europe and the United States. The cost to the US health care system alone was estimated to be around $8 billion per annum. These figures are likely to increase steadily as the average age of the population increases, to an estimated 6.26 million annually within the next 50 years (Melton (1993)).

As a person ages, their bone strength can decrease due to osteoporosis. This is the loss of bony tissue resulting in so called 'brittle bones', common particularly in post-menopausal white women (Hinton *et al.* (1993 & 1995)). This age related bone loss is an important factor when assessing the optimum treatment in fracture fixation (Cooper *et al.* (1987)). In conjunction with age, as the gait becomes more unstable, it increases the risk of fracture further, due to falling. However less than 5% of falls in the elderly result in femoral fracture (Greenspan *et al.*(1994) & Cummings *et al.* (1994)). Birge *et al.* (1993 & 1994) discussed the relationship between osteoporosis (bone fragility) and falling (trauma) with reference to hip fracture. The exponential increase in hip fractures with age compared with a smaller increase in the rate of falls, led them to conclude that hip fractures must also be influenced by other factors, most significantly the decline in mental function.

It has been reported that approximately 8% of all elderly females in the UK sustain a proximal femoral fracture and as a result 2% die (Bannister *et al.* (1989)). The mortality rate has been reported to be 14% for the first year after treatment, compared to only 9% in a similar age group of the normal population (Kenzora *et al.* (1983)). The mortality was reported to be significantly affected by the preoperative medical condition of the patient. Parker *et al.* (1993) attempted to predict the mortality after hip fracture in terms of the patients mobility before fracture and their mental test score, developing statistical data for percentage chance of survival at one year.

Treatment of hip fractures has become a significant consideration in the health care of the nation both in terms of achieving successful fracture fixation and financial resources. The Royal College of Physicians reported in 1985 that 20% of all the UK's orthopaedic beds were taken up by cases of proximal femoral fracture, of which 50% were treated by internal fixation (Calvert (1992)). In 1992, the typical cost of femoral fracture treatment for each patient, including operation, rehabilitation and follow-up clinic visits was estimated at approximately £3300. (Parker *et al.* (1992)).

An increasingly common determinant for the success of any particular treatment is the length of hospitalisation of the patient. Improvement in the rehabilitation and recovery rates from femoral fracture could reduce both mortality and costs significantly. One way of achieving this is by assessing the optimum treatment and improving the success rate through identification of the failure modes and the possible causes of each one. Design practice for fracture fixation devices could thereby be enhanced.

1.2 Currently Available Fracture Treatment

One method for the treatment of hip fractures is traction, a non-operative treatment (Horn *et al.* (1964)). After bone fracture, the muscle attachments remaining on the individual fragments exert pulling forces, which can lead to a misalignment of the fracture ends. Traction is the application of a force to counteract the natural tension in the surrounding tissues and ensure that the fractured femur is correctly positioned during the early stages of healing. The minimum period of traction required for this technique is typically 6-10 weeks and the resulting mortality rate has been reported to be as high as that of operative techniques. Weight bearing on the injured limb is not recommended before 12 weeks post fracture and as a result this treatment is very resource intensive.

Hemiarthroplasty or prosthetic replacement of the femoral head is another available treatment. Hemiarthroplasty has been recommended for patients over the age of 75 with a severely displaced fracture (Maxted *et al.* (1983)), regarded as a 'quick and easy' operation. However the reported failure rates of this treatment have been as high as 70% (Raine (1975)) and many are followed by a total joint replacement after several years.

Three types of internal fixation systems are commonly employed to stabilize hip fractures prior to fracture healing (Fig 1.1). Cannulated screws can be used in a formation to pin the femoral head into place (Tan *et al.* (1993)). Fixed length nail plates such as the Jewett Nail or the Mclaughlin Nail Plate, are an alternative but have a tendency to bend or penetrate the cortical bone of the femoral head, known as cut-out. This failure of the fixed implant results in one in six operations being repeated (Bannister (1989)). Sliding hip screws or sliding nail plates are the latest development in fracture fixation. They consist of an external plate fixed to the lateral side of the femur by a number of cortical bone screws and a lag screw inserted centrally into the femoral head, which has the ability to slide within a barrel to reduce the fracture gap. A number of trials have been undertaken comparing these devices with fixed nail plates with favourable results (Jensen *et al.*(1980), Bannister *et al.* (1990), Jacobs *et al.* (1976)).

The failure rate of the sliding implant has been reported to be between 5% and 20%, in a number of clinical trials. (Davis *et al.* (1990), Nue Moller *et al.* (1985)). These devices encourage load transfer down the proximal femur, the ability to allow impaction of the bone across the fracture site resulting in a better distribution of load between the implant and the bone (Mahomed *et al.* (1994)) (Fig 1.2). This can induce improved union of the fracture site and reduce the tendency of the lag screw to cut-out of the femoral head. However, cutting-out is still the most common cause of failure reported, as seen in the fixed implants. It has been suggested that the sliding lag screw component jams within the barrel of the device and the resulting implant acts as a conventional solid nail plate type implant. The correct positioning of the lag screw within the femoral head is a major factor in the success of the device and the skill and technique of the operating surgeon is of considerable importance.

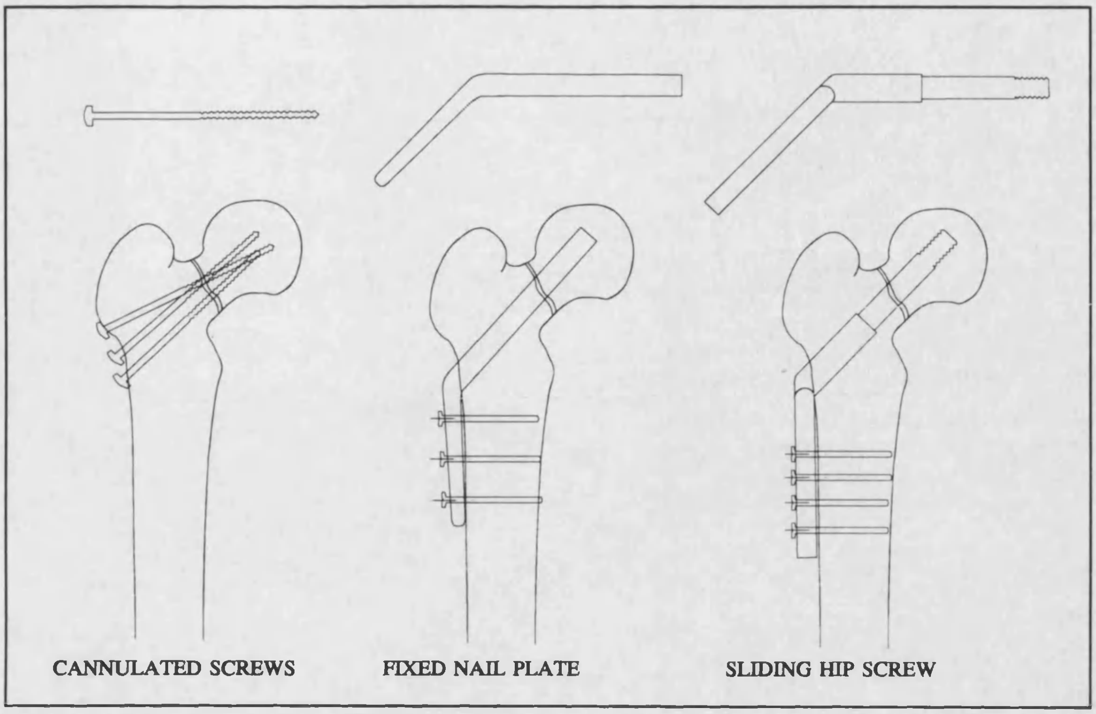

Fig 1.1 - Three alternative internal fixation systems for fractures of the femoral neck

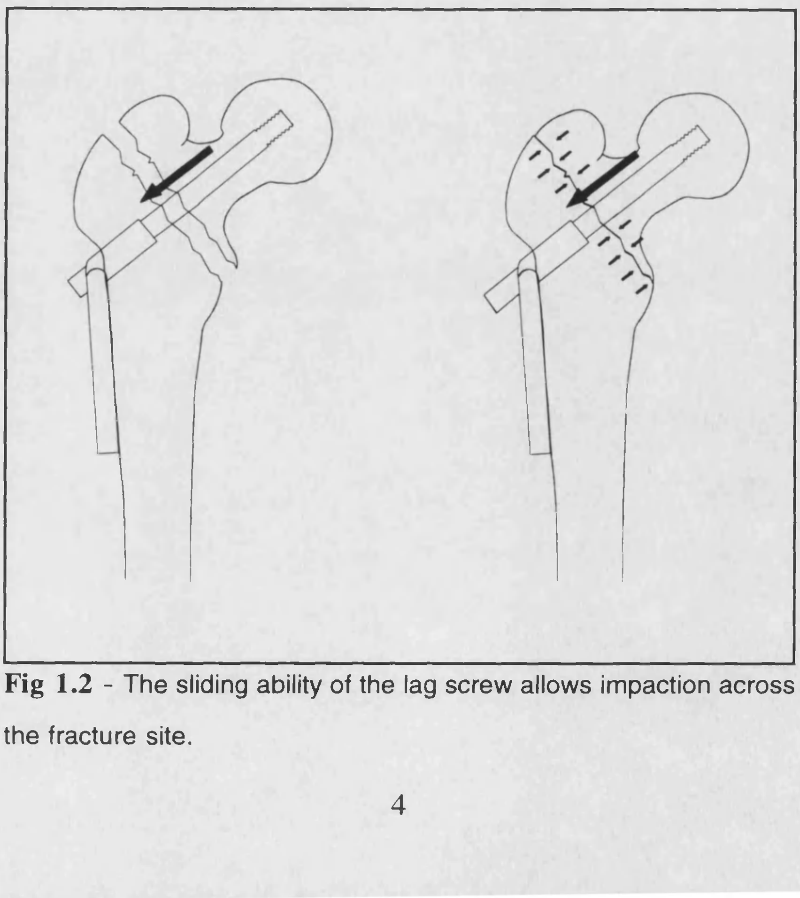

Fig 1.2 - The sliding ability of the lag screw allows impaction across the fracture site.

The success of any implant is therefore due to a combination of skills and expertise in both medical and bioengineering fields, as the design of the implant and the biocompatability of the implant material are also important considerations.

1.3 The Sliding Hip Screw

Two designs of sliding hip screw are investigated in this study, the Dynamic Hip Screw (Synthes) and the Gamma Locking Nail (Howmedica) (Fig 1.3). The Dynamic Hip Screw (DHS) is the more conventional hip screw design as outlined in section 1.2. It consists of a plate secured to the lateral side of the proximal femur by a number of cortical screws. A lag screw is inserted into the femoral head through a barrel at the top of the plate. There are two flats on its shank to prevent rotation within the barrel and a self cutting screw thread for ease of insertion. A relatively large incision must be made down the lateral side of the leg to position the plate onto the bone.

The Gamma Nail consists of an intramedullary nail which is passed down the proximal femoral canal, with two distal locking screws which can be used to prevent movement of the nail within the shaft. The lag screw has four hemispherical grooves at 90° to each other along the shaft, and a self cutting screw thread. It is passed through a hole in the nail into the femoral head and a set screw is located in one of the grooves to prevent rotation.

The Gamma Nail is a more recent introduction to the sliding hip screw family. It has a mechanical advantage over the DHS as a result of the reduced bending arm formed by the lag screw, associated with the medial positioning of the nail (Rosenblum *et al.* (1992)). The DHS creates additional stress on the cortical bone screws from the lateral positioning of the plate in relationship to the line of weight bearing of the femur. The Gamma Nail also has a surgical advantage over the DHS, since the implantation of the device is by a semi-closed insertion technique, ie. two small incisions, for the nail and the lag screw individually.

A variety of clinical failure modes have been reported for these two implants in addition to the lag screw cut-out.

Fig 1.3 - The Gamma Locking Nail (left) and Dynamic Hip Screw (right).

These include the DHS plate pulling off the femoral shaft or the lag screw bending or breaking. The Gamma Nail has been reported to cause femoral fractures below the nail or around the distal screws.

1.4 Project Aims

There are currently no published guidelines or standards with regards to testing the majority of orthopaedic implants associated with the field of trauma. The most relevant to the subject of hip fracture fixation is BS3531:Part 15, which outlines the materials that are permitted, along with dimensions and packaging for nail plates. New stricter regulations for all implants are being introduced in Europe by regulatory authorities in line with the US Food and Drug Administration (FDA), which will increase the need for relevant biomechanical evaluation of the implants prior to clinical testing. A vast range and complexity of tests is reported in the literature, often reaching contradictory conclusions, making it difficult to make direct comparisons between the studies for different implants.

This study aims to review current literature, to understand the depth of the problems associated with sliding hip screws, in terms of the failure modes and the frequency and conditions under which they are most likely to occur. By recreating each of these failures under simplistic laboratory conditions, the failure loads could be estimated and strain analysis used to investigate the load transfer mechanisms between the implants and the bone and the possible effect of this on the failure modes.

It is postulated that sliding hip screws cannot be realistically tested under static loading conditions. It is intended to test the implants in isolation under a variety of static and dynamic loading conditions to examine the effect of these on the performance of the sliding implants, data from a clinical trial providing individual clinical situations for biomechanical comparisons. From this study a protocol will be developed allowing realistic tests to be undertaken on new and existing sliding hip implants prior to clinical trials or general release. This information should reduce the failure rates associated with these devices, improve patient care and reduce health care costs.

Chapter 2

LITERATURE REVIEW

2.1 The Hip Joint

2.1.1 Functional Anatomy of the Hip Joint

The hip joint is one of the largest and most stable joints in the human body. It is comprised of the head of the femur which sits within the acetabulum of the pelvis, forming a ball-and-socket type configuration. The head of the femur forms two thirds of a sphere, covered by articular cartilage of varying thickness with a resulting range of strength and stiffness over the surface. The cavity of the acetabulum is also covered with a layer of articular cartilage, which distributes the load over the contacting surface, forming a bearing surface to reduce friction and wear of the joint itself (Nordin *et al.* (1989)).

The joint is surrounded by groups of large muscles. The Gluteus Maximus, the Iliacus and Psoas muscles, used for extension and flexion and the Gluteus Minimus and the adductor muscles, used for abduction and adduction of the joint (Fig 2.1). The muscles and ligaments around the joint are important in the overall transmission of load and must be considered when calculating the forces across the joint. The angle of the femoral head with the femoral shaft, known as the femoral neck angle, influences the freedom of movement of the joint and determines the perpendicular distance to the point of muscle attachment on the greater trochanter. In the frontal plane the femoral neck angle is around 125° (Fig 2.2). In the transverse plane the head is angled at around 12° with the distal condyles and it is deviation from this angle which results in internal or external rotation of the leg during walking.

The femoral head and neck forms a highly complex structure composed of cancellous bone, in the form of trabeculae, surrounded by a thin layer of cortical bone.

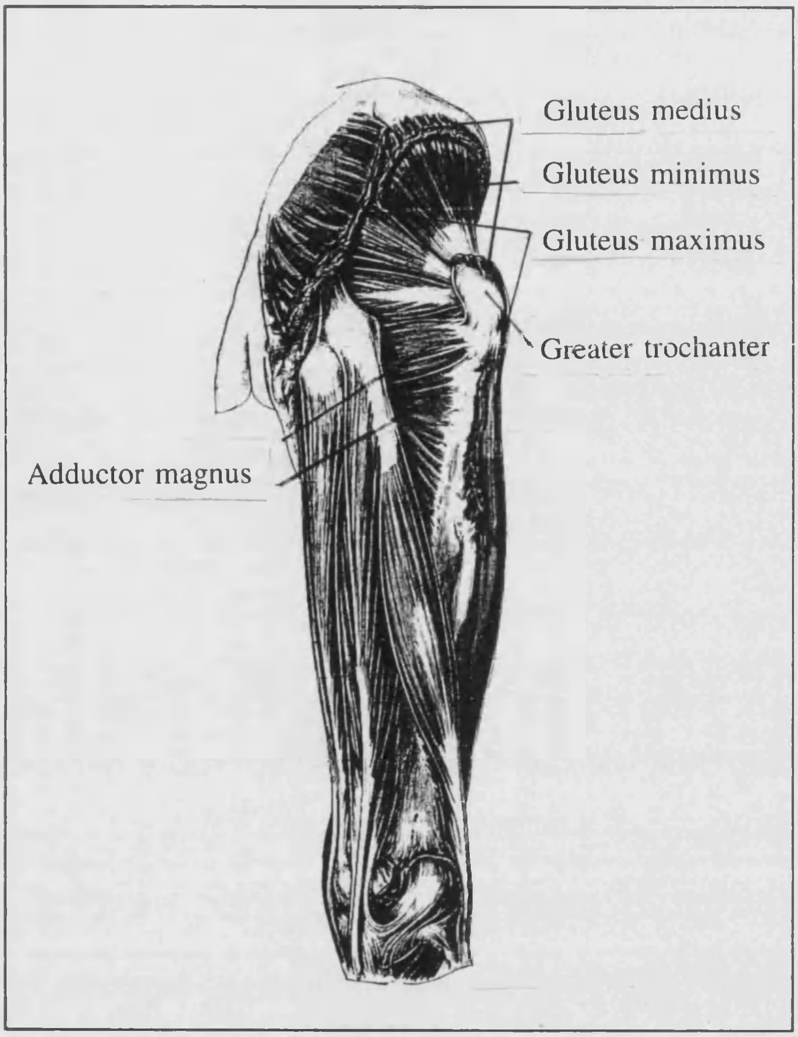

Fig 2.1 - The anatomy of the hip joint showing some of the major muscle groups.

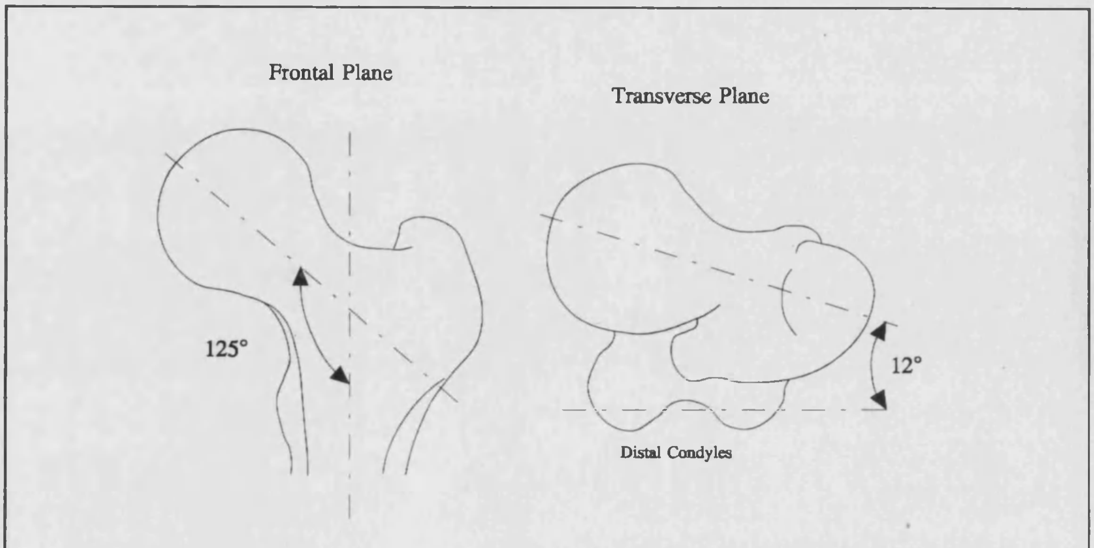

Fig 2.2 - Illustration showing the femoral neck angles in the frontal and transverse planes.

Trabeculae are thin bars of bony tissue, organised along the lines of maximum compressive and tensile stresses and aligned with the angles of joint reaction forces on the femoral head. They support the hip joint forces and transfer the load from the head, through the neck, down to the thicker cortical bone layers of the femoral shaft. The trabecular architecture was first explained by Wolff (1891) who compared the behaviour of the femoral head and neck structure to a curved crane supporting a vertical load.

The four major groups forming the trabeculae arches are the following (Fig 2.3):

i Principal compressive group - extending from the medial cortex of the shaft to the upper portion of the head of the femur, forming the largest group.

ii Secondary compressive group - extending from the medial cortex of the shaft upwards and laterally towards the greater trochanter and upper portion of the neck.

iii Principal tensile group - extending from the lateral cortex below the greater trochanter, curving around the neck of the femur to the lower portion of the head of the femur.

iv Secondary tensile group - extending from the lateral cortex below the principal group upwards and medially ending irregularly across the mid-line.

2.1.2 Biomechanical Properties of Bone

Bone can be considered as a composite material, where a strong brittle material is embedded within a weaker flexible one. The outer cortical bone is stiffer than the cancellous inner bone, with the ability to withstand greater stress but significantly less strain. Bone itself is made of minerals and collagen, which is a fibrous tissue made from proteins, and the combination of the two predetermine the mechanical properties of the material. A small variation in the mineral content of bone has been shown to produce large variations in the failure stresses and the modulus of elasticity of the structure (Currey 1969). As bone ages, its mineral content increases which results in the bone becoming more brittle and at the same time the overall bone density decreases as the bone is resorbed, lowering the bone strength (Tencer *et al.* (1994)).

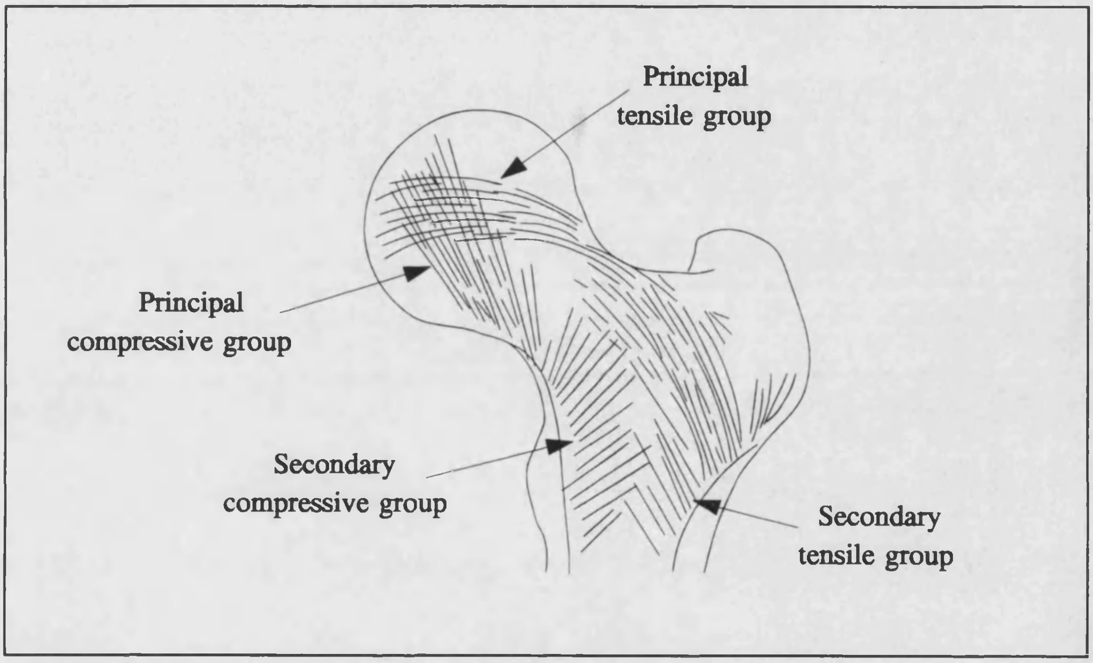

Fig 2.3 - Illustration of the four major trabeculae groups within the femoral head.

The overall mechanical behaviour of bone is dependent on the geometric shape, the loading rate, type of loading applied and the frequency rate. Under mechanical testing, the maximum stress can be seen to occur in a plane perpendicular to the applied load due to the anisotropic properties of bone (Frankel *et al.* (1970)). Long bones such as the femur, are subjected to high bending moments, therefore high tensile and compressive stresses. During walking, bending moments are applied to the femoral neck which are counteracted by the muscle groups to reduce the overall stresses and allow higher loads to be sustained.

Bone is also a viscoelastic material, being stiffer and able to sustain higher loads at increased loading rates. This is important when considering the amount of damage that occurs at a fracture site. High impact injuries produce more comminuted fractures than simple falls due to the larger amount of stored energy. Therefore the type of fracture experienced by a bone can be indicative of the loading mode that caused the fracture, but *in vivo* the exact loading mode experienced by any bone is very complex.

The progressive loss of bone density as part of the aging process is particularly significant in the trabecular bone of the femoral neck. The trabeculae are slowly resorbed, reducing the ability of the femur to absorb impact loads (Tencer *et al.* (1994)). Excessive forms of this bone reduction are more common in elderly women and is known as osteoporosis. Osteoporosis is one of the leading factors influencing the risk of hip fracture and the outcome of any fracture treatment. Opinions are divided on whether by estimating the degree of osteoporosis that is present in a particular case, one can enhance the ability to make a prognosis of the treatment and the final result.

A common system used to classify the level of osteoporosis is the Singh Index (Singh *et al.* (1970)) which relies on grading the appearance of the primary and secondary tension and compression trabeculae within the femoral head and neck, from anteroposterior X-ray projections (Appendix B). The usefulness of the system is constantly debated due to the variation in X-ray quality and the subjective nature of the readings (Laros (1980)). Engh *et al.* (1985) utilized a simplified system of categorising the femora using only three grades from the Singh Index in an attempt to overcome the variability.

Stulberg *et al.* (1987) compared the Singh and Engh Indices with a histologic assessment of bone structure during a study looking at the outcome of total hip replacements in relation to bone quality. A biopsy was performed at the time of operation to remove a section of bone from the iliac crest, the region between the two principal trabeculae. These specimens were embedded in bone cement and then sectioned and digitised to enable measurements of the trabecula bone volume to be established. No correlation was found between the roentgenographic and histologic evaluation techniques, suggesting clinical evaluations are unreliable.

Matthews *et al.* (1992) attempted to predict the outcome of total hip replacements using preoperative imaging to assess the mechanical integrity of the proximal femur. They compared subjective measurements from the radiographs of 10 patients with the compressive mechanical properties and bone volume measurements taken from core samples. Again they found the subjective assessments to be inaccurate and unreliable, but suggested a system of measuring the bone density using single photon absorptiometry as an indicator for treatment success.

To compare non-invasive techniques, Leichter *et al.* (1982) compared bone mineral content (BMC) measurements (the absorption of a photon beam), bone density readings using a Compton scattering technique (the radiation at 90° from a photon beam) and Singh Indices with mechanical strength, for paired cadaveric specimens. They found that the bone density and mineral content were directly related to the shear stress at failure, particularly bone density. They concluded that the Singh Indices could have no clinical value. A study by O'Delaere *et al.* (1989) destroyed the principle tensile and secondary compressive groups in one of each matched pair of cadaveric femora. They concluded that the bone density was the best indicator of the failure load, but that the removal of the trabecula reduced the failure loads by 50%, suggesting that the Singh system of grading the remaining trabeculae should be an indication of the outcome.

The bone mineral content of the spine was measured by Firooznia *et al.* (1986), in women with hip fractures and or spinal fractures, using a system of computed tomography. They assumed that bone loss in the spine was the same as that in the femoral neck, concluding from their study that femoral fractures were not directly correlated to bone loss. Milligan (1965) attempted to establish the outcome of the internal fixation of femoral neck fractures by staining the femoral head per-operatively to estimate the bone quality. By using Kilton Fast Green dye to stain the bone, the author felt it was a reliable system to predict whether the head was live or dead. The final outcome in the dead heads was consistently worse than the other group. He did however mention a disadvantage in the system in that the patients skin becomes bright green for 48 hours as the dye was excreted.

The quality of the bone within the femoral head is clearly related to the degree of osteoporosis in the patient, whatever system is used to identify it. The condition is common in the population in which femoral fractures are most often found. The success of any internal fixation device used to treat femoral fractures is also more prone to failure in these cases, due to the lack of bone support. A simple, reliable system of classifying osteoporosis would be beneficial before the selection of all fracture treatments.

2.1.3 Loading Configuration Associated with the Hip Joint

The range of motion of the hip joint occurs in three planes; sagittal (flexion/extension), frontal (abduction/adduction) and transverse (rotation) (Fig 2.4). The most significant of these being flexion which can range from 0 to 140 degrees (Nordin *et al* (1989)).

The forces experienced by the hip joint have been reported to be between 2.4 times body weight (Inman (1947)) and 2.7 times body weight (Frankel *et al.* (1970)), for a single leg stance. This figure can increase to as much as seven times body weight during a walking or running phase (Paul (1967)). In order to determine the loads acting at the joint during a single leg stance, muscle loading must be considered. The most significant muscles supporting the hip are assumed to be the gluteus muscle groups, their share of the load estimated by their relative volume (McLeish *et al.* (1970)). A single resultant force was established by assuming the line of action and position of the relevant muscles (Fig 2.5).

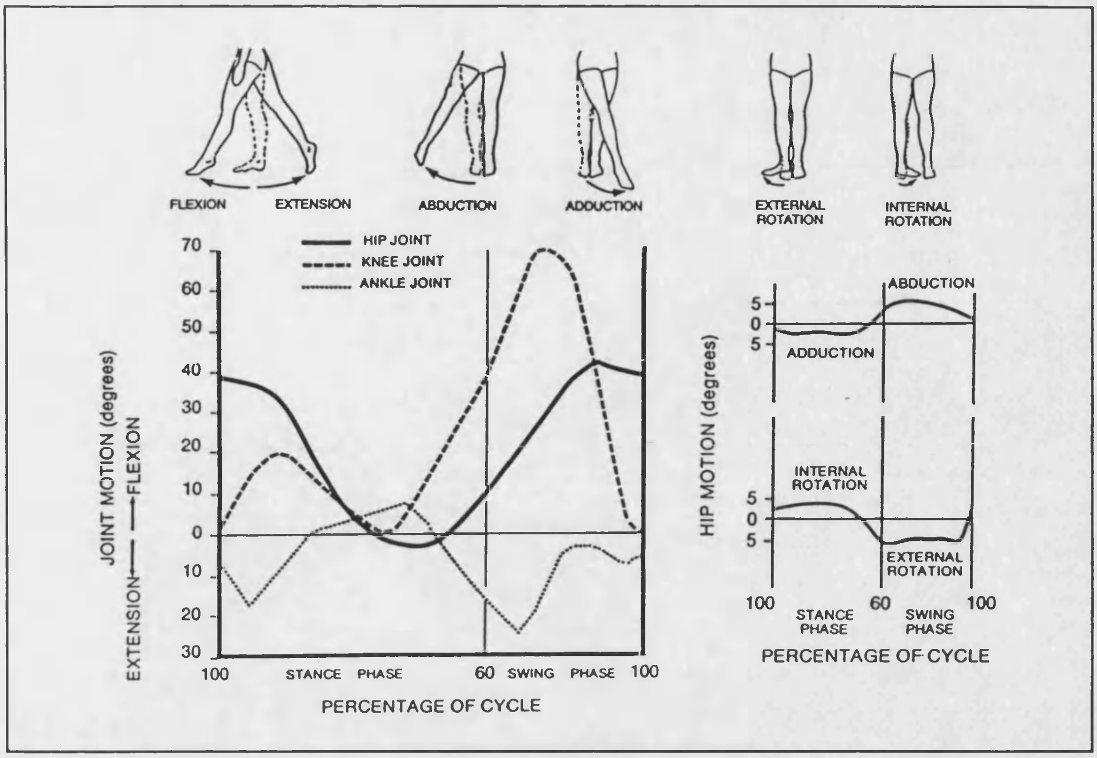

Fig 2.4 - The range of motion of the hip joint (adapted from Nordin *et al.* (1980)).

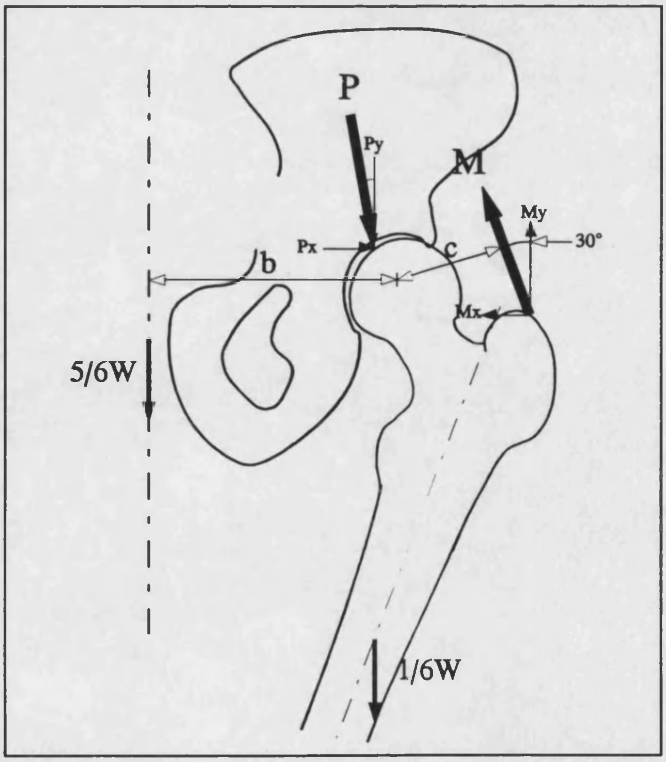

Fig 2.5 - Simple equilibrium based analysis of hip joint loading.

Moment equilibrium $M = (5/6W * b)/c$

As $b = 2c$, $M = 2W$

$M_x = M\sin30°$ $= W$

$M_y = M\cos30°$ $= 1.7W$

Force equilibrium $M_x - P_x = 0$

P_x $= W$

$M_y - P_y - 1/6W + W = 0$

P_y $= 2.5W$

Therefore P $= 2.7W$

@21°

Where M = resultant muscle force

M_x & M_y = components of muscle force

P = joint force

P_x & P_y = components of joint force

W = Body weight

The first recorded direct measurement of hip joint forces was by Rydell (1966), who implanted a strain gauged prosthesis into a volunteer, with the wires emerging through the skin. The transducer allowed measurement of the three components of force and bending moments on the neck of the femur to be determined. He stated that under normal walking the forces were 2.5 - 3.5 times body weight through the hip joint. More recent studies by Bergmann *et al.* (1990, 1991 & 1992) have used much safer telemetric in-vivo measurement systems, utilising an instrumented hip prosthesis. They measured forces at the hip post-operatively with the patient walking with two crutches, one crutch and for unaided walking, resulting in measurements of 2.0, 2.4 and 2.7 times body weight respectively. In any engineering analysis, the direction of the force is as important as its actual value. Paul *et al.* (1985) established the direction of a resultant load for a hip joint during a walking cycle. It is these loads, because of their offset angle, which will create the twisting or rotation force on the shaft of the femur (Fig 2.6)

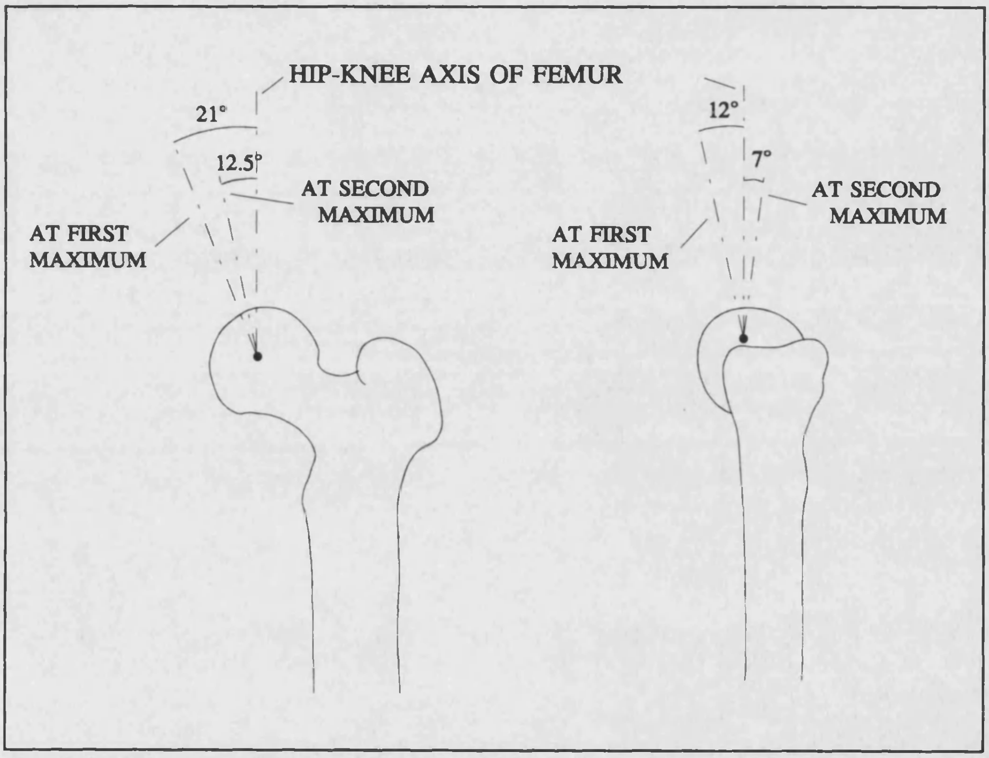

Fig 2.6 - Direction of hip joint forces relative to the proximal femur in the frontal and lateral views.

McFadyen *et al.* (1988) completed a study of stair ascent and descent using force plates and EMG measurements of the muscle groups. They established that the moment pattern was of a similar shape to level walking but of greater magnitudes. Bergmann *et al.* (1991) measured the hip forces for ascending and descending stairs in the same patients as in the earlier level walking studies. The descending loads were found to be comparable to level walking but the ascending loads were considerably higher. They also established that it was the style of walking that affected the loading rather than the shoes or floor material (Bergmann *et al.* (1990)).

The Grieve Equation (Grieve (1968)) was derived to relate the stride length with the walking speed and cycle time. By studying people walking at a range of speeds, the following equation for an individual adult was derived:

$$f = Þ \, V'^{ß}$$

where f = number of cycles per second

V' = relative speed (related to stature)

Þ = a constant of between 61-65 for males and 65-73 for females

ß = a constant of 0.58

This equation was considered to be a reflection of the rhythm of movement and the author felt that visual impressions were an important part of any quantitive analysis. The loading and movement of the hip joint is significantly affected by the speed of movement, so this is an important factor in any complete assessment.

Rodosky *et al.* (1989) examined the mechanics of rising from a chair on the forces at the hip. They established that the motion and moments about the hip joint were greater than those during stair climbing or walking, but that they were not influenced by the height of the chair. Johnston *et al.* (1970) simply analysed the motion required for a range of activities, including tying shoes, sitting, stooping, squatting and climbing stairs, using an external frame system of potentiometers. From their data of 36 patients they could determine the flexion required at the hip for given activities.

Frankel (1960) investigated the loading through the joint after insertion of an instrumented nail plate within a proximal femur, in cadaveric studies. This showed the load experienced by the implant was 25% of the resultant load of a person during a single leg stance. The remaining 75% of the load was thus transmitted through the bone across the fracture site. The implant transmits the load down the femur, therefore reducing the loading at the fracture site. If the implant were to experience 100% of the load, the fracture healing would be seriously delayed due to non-physiological loading leading to poor bone repair.

A number of studies have looked at the gait of a patient after fractures of the femoral neck (Walheim *et al.* (1990) & Baker *et al.* (1991)). Under normal conditions of fracture healing, only 25% of patients had returned to normal gait 6 months post-operatively. This suggests that the loading through the joint was reduced due to external aids during fracture healing. This was found to improve if the patients were 'taught' how to walk again on a treadmill, during the healing phase.

After fracture of the hip, relatively large forces must be accommodated by the fracture healing device postoperatively. It has been shown that these can occur during anything from transferring from the bed, in and out of chairs and walking. Even with external support, the forces experienced are still high, and these must be taken into account when designing any new implant and in the testing of any existing implants.

2.2 Classification of Hip Joint Fractures

Peritrochanteric fractures occur around the trochanteric region of the femoral neck. They are categorised by the position of the fracture lines in relation to the greater and lesser trochanter, into subtrochanteric and intertrochanteric fractures. These are then subdivided into two groups, stable or unstable. An unstable fracture is one that still tends to fall apart due to physiological loads even when reduced.

The assessment of the stability of a fracture is an important consideration for any surgeon when considering the treatment to be employed. Many surgeons use a variety of implants, each one for different fracture configurations (Meissner *et al.* (1989), Caudle *et al.* (1987)), providing different degrees of stability.

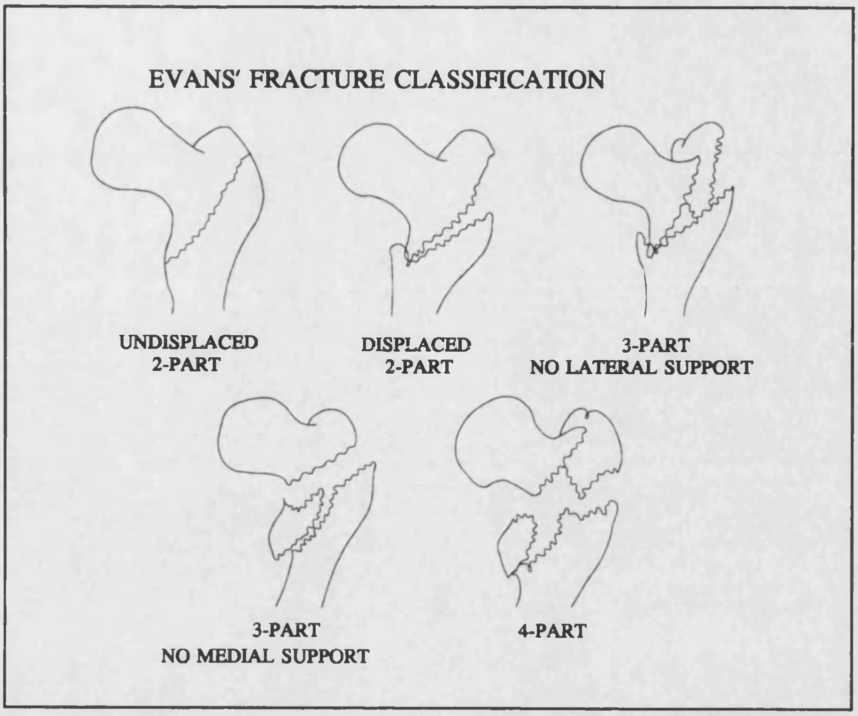

Fig 2.7 - Illustration of the Evans' fracture classification system.

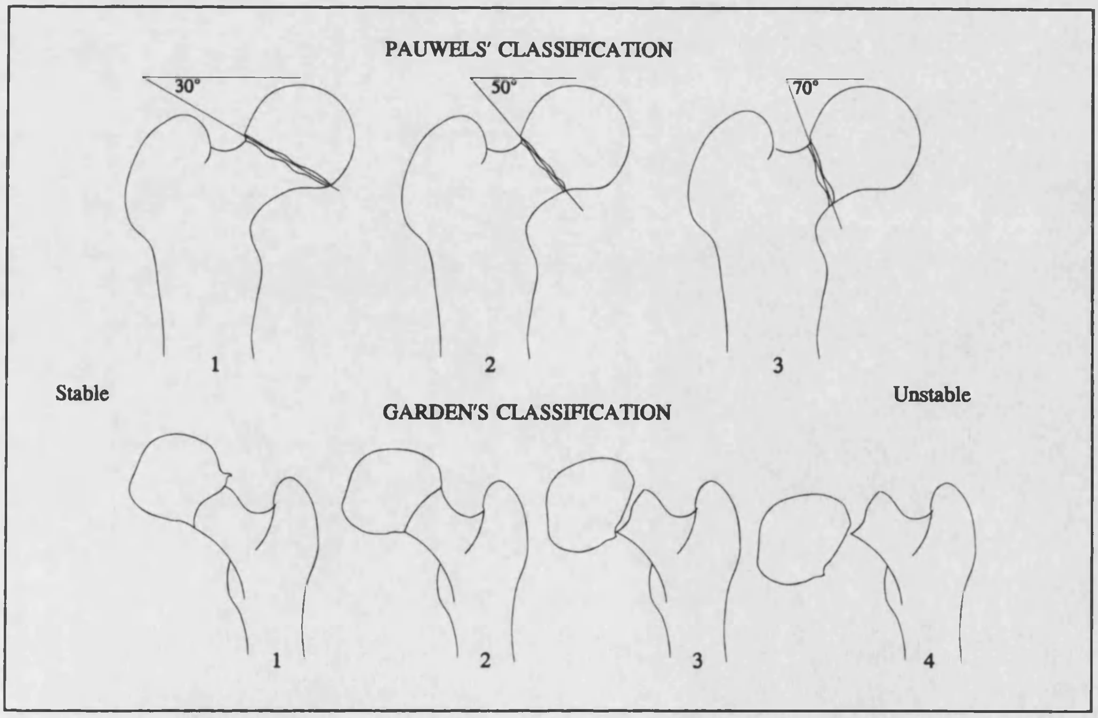

Fig 2.8 - Illustration of Pauwels' and Garden's fracture classification systems.

There are a variety of methods of categorising an intertrochanteric fracture. In 1949, fractures were classified as stable or unstable by Evans, relating to the behaviour of the fracture under traction (Fig 2.7). The same prediction can still be applied to the behaviour after internal fixation. The Garden classification (Garden (1961)) is based on the degree of displacement of the fracture site (Fig 2.8). They further categorised femoral fractures into the number of parts, that is the degree of fragmentation of the fracture.

The Pauwels' classification (Pauwels (1935)) (Fig 2.8) is dependent on the angle of inclination of the fracture line across the neck of the femur. The more vertical fractures are considered to be unstable due to the high shear forces, which would place all the force across the implant used to secure them.

2.3 Methods of Fixation of Hip Joint Fractures

From as early as 1878, fractures of the hip have been treated by internal fixation as an alternative to the external body cast, in an attempt to reduce muscle wastage and encourage bone healing by early weight bearing. The first implants were no more advanced than normal wood screws which lead to infections and corrosion of the implant itself (Tronzo (1974)). The first specifically designed implant was not reported until 1931, when Smith-Peterson designed the tri-flanged nail which passed along the femoral neck into the femoral head (Smith-Peterson *et al.*(1931)). This closed nailing technique is used today with the use of image intensifiers and improved surgical techniques to position the implant.

McGibbon was the first surgeon to add a side plate to the Smith-Peterson Nail which greatly increased the rate of fracture union. These early nails were not well designed however, and they often broke. The majority of improvements to implants were being made by the surgeons and no consideration was given to the biomechanics of the device. In 1941 Jewett (Jewett (1941)) designed the one piece nail which reduced the problem of the old nails backing out of the femoral head. This implant is still used today, although it has been updated.

The sliding device has been in existence since the 1950's when Richards saw the potential of a lag screw placed in the femoral head, based on an implant used by the German surgeon, von Pohl. They added a compression screw to the design to aid impaction of the fracture site. In 1959 Charnley (Charnley (1959)) introduced his hip screw which created dynamic compression across the fracture with an internal spring. This allows dynamic movement in the axial plane of the screw whilst maintaining the torsion and bending rigidity of the device.

A fracture heals in three phases; inflammatory, reparative and remodelling. The initial phase is the accumulation of a haematoma or blood pool. Within 24 hours this blood clot begins to organise itself into a fibrous mesh that seals the damaged blood vessels. In the second phase a 'bridge' of hard tissue forms as a callus. Cartilage and fibre bone forms, to increase the mechanical stability of the fracture prior to formation of new bone. The callus increases the second moment of area and hence the stiffness of the bone, due to the increased distance from the neutral axis. The final phase is the remodelling of the bone structure to its original shape and form over a longer period of time. The new bone grows inwards from the surface of the callus, replacing the cartilaginous tissue, until the callus is remodelled with no evidence of the fracture. To complete this third phase the fracture must be subjected to normal stresses. The reduction of the fracture gap seen with dynamic compression leads to micro-movement and promotes this bone healing process (Mow *et al.* (1978)).

The sliding hip screw is rapidly replacing the nail/plate system in all hospitals today (Kohlmann *et al.* (1987)). The intramedullary sliding hip screw is a relatively modern design (Fig 1.3), Howmedica introducing their Gamma Nail and Richards their IMHS (IntraMedullary Hip Screw).

2.4 Biomechanical Studies in Hip Fracture Fixation

Kaufer (1979) outlines the five variables which affect the success or failure of any fracture fixation as bone quality, implant placement, fracture reduction, fragment geometry and implant design. Biomechanical investigations have been performed looking at each of these parameters, with a variety of results. The results themselves are often affected as much by the test methodology as by the parameters tested.

From a large number of published clinical studies it is evident that cut-out of the lag screw through the femoral head is a significant failure mode associated with sliding hip screw devices (section 2.5). One reason for this is that the lag screw fails to slide within the barrel, causing the implant to act as a one piece device, cut-out being the typical failure of solid one piece implants. Cutting-out of the lag screw causes considerable pain to the patient, particularly if the acetabulum is penetrated, and usually requires a further operation to withdraw the implant. Two opposing arguments to explain cutting-out have been suggested in the literature (Simpson *et al.* (1989)); that the bone quality determines whether the screw will slide or that the position of the screw within the femoral head, ie. implant placement, is the deciding factor.

2.4.1 Bone Quality

Smith *et al.* (1989) performed a cadaveric study to determine the load to failure by screw cut-out in relationship to the bone density. For each of the 22 cadavers used, three independent judges assessed the Singh Indices and repeated the readings on a number of occasions, to establish an average subjective assessment of the bone quality. The bone density was also accurately measured using a regional bone mineral density computed tomographic protocol, established by the author. Each cadaver was loaded until a femoral neck fracture occurred and then implanted with a DHS and loaded to failure, at 24° to the vertical at a rate of 12.7 mm/min. They found that the failure loads for the implanted cadavers were directly related to the bone mineral density readings, but the Singh Indices were very unreliable both as an indicator and in reproducibility. As previously indicated, Singh Indices were designed to be a simple assessment of the level of osteoporosis present in the femoral head region, estimated from basic radiographs. Unfortunately, the expensive computed tomography used in this study is not always accessible in the clinical situation.

A similar study by Shah *et al.* (1993) measured the bone mineral density of twelve pairs of cadaveric femora. The right femur from each pair was fractured at 55° across the femoral neck and implanted with a 135° DHS. Both the left and right femurs were then loaded to failure at 23° to the vertical at a rate of 5mm/min. A direct correlation was found between the failure loads of both the test group and the control group, with the bone mineral density. The failure loads for the implanted cadavers were found to be 50% less than the matching control femurs. They attributed this to the simulated femoral fracture breaking the lines of the load bearing trabeculae, so more load was taken by the femoral head resulting in screw cut-out. This supports the idea of the Singh Indices as an assessment of bone quality, assuming the readings could be acquired more accurately. The authors continued by questioning the viability of early weight bearing using these implants, suggesting that one should wait until a bony union has formed and the trabeculae were beginning to restructure.

Goh *et al.* (1994) tested 'healed' and 'fractured' cadaveric groups within their test protocol, comparing the failure loads with the DHS applied to intact femora and artificially fractured femora. Both groups were loaded at 24° to the vertical at 5mm/min and the failure loads were directly related to the bone mineral density, found by dual energy X-ray bone densitometry. The variation in failure loads between the two groups, led the authors to suggest that the bone quality prior to fixation should be a criterion for the post-operative management.

A study into cut-out by Richards *et al.* (1990), physically measured the bone density of individual femurs in terms of bone compression strength. Femoral heads were removed from paired cadavers and a core of bone removed from each femoral neck. These cores were then compressed to 50% of their initial length to ascertain an indication of bone strength for each cadaver. DHS and Pugh Nail lag screws were implanted into the isolated femoral heads which were mounted onto nylon shafts. An incremental load was applied to the heads until the cortical bone layer failed. The study looked at the failure load of a tri-flanged lag screw with the more common threaded lag screw, comparing the failure loads in terms of bone strength to the surface area of the screw thread. The failure load for the tri-flanged screw was found to be 70% higher than that of the more common threaded screw when adjusted for bone strength, which they directly associated with its larger screw surface area. No consideration was given to the respective holding power of the two lag screw designs or the dimensions of the overall lag screws in terms of the volume of bone they replaced.

A simple study by Hertz *et al.* (1985) examined the torque required to force the lag screw to cut-out of the femoral head. DHS lag screws were implanted into cadaveric femoral heads, and the required torque measured using a precision torque wrench. They established that a greater torque was required for cut-out in bone from younger patients, but no other evaluation of bone quality was performed. The aim of the study was to examine the lag screw distance from the cortical bone that would lead to a reduction in bone fracture during insertion, which was found to be a minimum of 10mm. A simple screw test was performed by Crowell *et al.* (1985) to determine if there was an optimum position within the head were the screws would have the most purchase. They found that the central and lateral regions, where the trabecula densities within the femoral head were greatest, provided the most support and resulted in the highest forces for screw pull out. Fixation rigidity and strength of the implanted lag screws would be a factor in the risk of cut-out.

During the operative procedure, the lag screws would be positioned under an image intensifier with two views available to the surgeon, anteroposterior and lateral. It is not always clear from these images if the lag screw is within the femoral head post-operatively (Nordeen *et al.* (1993)), so some knowledge of the forces required to pierce the cortical bone and the optimum position within the head would be highly desirable to the operating surgeon.

2.4.2 Implant Placement

To identify a relationship between the operative position of the lag screw within the femoral head and the subsequent cutting out, Parker (1992) studied radiographs of 225 patients of which 25 cases had failed. He identified the regions of high risk as being superior or posterior (Fig 2.9), placing a significant importance on surgical technique in the overall success of the device. A similar study by Wu *et al.* (1991) highlighted the same optimum screw position, stressing the importance of the tip of the screw remaining 10mm from the cortical femoral head surface to reduce the risk of cut-out. The quality of the bone itself was not considered in these studies.

Larsson *et al.* (1990) undertook a retrospective study looking at the lag screw position, considering a number of parameters as well as the screw position itself.

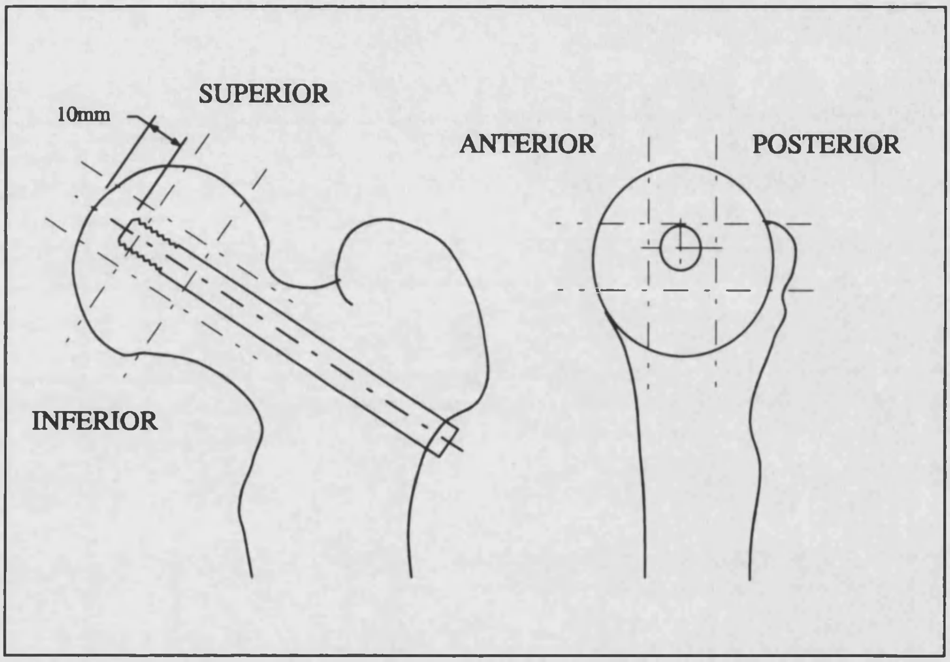

Fig 2.9 - Illustration showing optimum lag screw position within the femoral head.

These including Singh Index, fracture type and the reduction technique employed. Impaction of the fracture fragments postoperatively was measured from radiographs in each case to establish the amount of screw sliding that had taken place. They once again highlighted the importance of screw position, agreeing with the previous studies on which areas in the femoral head increased the risk of cut-out failure.

Rha *et al.* (1993) placed the most significance on the reduction technique used in their retrospective study. A large number of variables were considered in both these studies which would make any specific conclusions difficult, and as a retrospective study of clinical patients, the post-operative behaviour of each patient would also influence the success of the implant.

A prospective analytical trial by Galanakis *et al.* (1994) compared the migration of the DHS with a tri-flanged nail-plate, the DHS performing better overall particularly when placed in the middle third of the femoral head in both planes. The importance of this position was supported in a cadaveric study by Den Hartog *et al.* (1991). They compared a 150° and a 130° sliding hip screw, in combination with the position of the lag screw within the femoral head. The screw was inserted centrally or posteroinferiorly, the tip remaining 10mm from the cortical layer in both cases, and loaded at a rate of 5mm/min until failure occurred. The screw position clearly affected the failure mode of the sliding screws, the risk of cut-out was reduced by central positioning, but did not appear to affect the failure loads themselves. The larger plate angles increased the failure loads due to the lower bending moment on the lag screw. However, the authors felt this must be offset against the more difficult placement of these higher plate angles and the possible resulting superiorly placed lag screw. Hamm *et al.* (1988) compared the compression hip screw with the tri-flanged nail in a series of simple tests applying compression or a shear force to the femoral head until failure occurred. The conclusions were unsatisfactory, with no regard for the implant position or the quality of the bone itself. These can clearly be shown to be important parameters in any examination of the cut-out rates of implants from within the femoral head.

Kyle *et al.* (1980) examined the problem of cut-out from the perspective of screw sliding. In an experimental study they highlighted the problem of jamming of the lag screw due to friction in the sliding mechanism. The sliding hip screws were mounted in isolation in a test rig, with the lag screw axis vertical and a normal load applied horizontally to the lag screw to represent body weight. The load required to overcome friction was then defined as the sliding force. The study concluded that shorter lag screws and greater plate angles would reduce the risk of jamming. However, all the loads obtained throughout this study were high and would indicate that sliding of the screw would rarely occur under any conditions. In most clinical situations, this is evidently not the case as radiographs clearly indicate sliding of the lag screws has occurred under conditions of considerably lower loads than those shown in this study.

A continuation study by Kane *et al.* (1993) compared the jamming potential of an intramedullary nail with the earlier sliding hip screw plate system. They found that the intramedullary nail required greater forces to induce sliding and as such had a far higher risk of jamming, thus increasing the risk of cut-out. The test conditions between these two studies remained almost the same, as the loading rig was simply modified for the second series. The exception to this was the displacement rate of the applied sliding force, which had been reduced from 60mm/s in Kyle's study to 0.5mm/s. The authors dismiss the reduction of a factor of 100 in the application rate as insignificant, but loading rates are a major consideration in any test protocol.

A two-dimensional model of a repaired intertrochanteric fracture was used by Gill *et al.* (1989), to estimate the forces transmitted by the sliding implant at the fracture site. They hypothesised that increased loading of the implant would lead to higher stresses in the surrounding bone and a higher risk of failure. Several basic assumptions were made in the calculations, including a straight fracture line and conditions of equilibrium (section 3.5). They suggested that as the lag screw telescopes, the point of load application moves distally, reducing implant moment and improving the stress distribution in the surrounding bone. They also believed that high fracture angles, i.e. unstable fractures, would lead to high bone stresses. Their simple mathematical model agreed with the clinical situation, where unsuccessful results were associated with the higher fracture angles. Their aim was to assess the viability of any treatment from simple radiograph measurement of the fracture prior to surgery, but further analysis of the bone/implant contact stresses would be necessary to support their theory.

A practical solution to the problem of cut-out was looked at in studies by Choeka *et al.* (1995) and Claes *et al.* (1995), where the femoral head was filled with cement to provided extra support for the lag screw. The former study was a cadaveric study comparing the standard sliding implant with the 'dome plunger' system, which enables cement to be pumped along the hollow lag screw directly into the femoral head. The femora were loaded at 25° to the vertical at a rate of 10mm/min until failure occurred. No cut-out failures were observed in the dome plunger group. The other study explored the use of cement with the DHS, comparing a standard implant technique with one where a glass ionomer cement with a low polymerisation temperature, was injected into the screw hole of the femoral head prior to inserting the lag screw. Again the cement was found to reduce cut-out and migration within the head, by reinforcing the bone. Before this technique could be recommended as a realistic solution in the clinical situation, stringent trials must be undertaken to ensure that the early stability introduced by the technique does not lead to late complications. If the cement was to protrude into the fracture site itself, it could seriously interfere with the healing process.

The bone quality and implant placement are both influential on the cut-out frequency of the sliding hip screws, but a number of other clinical failure modes have been reported in the literature. These include the lateral plate pulling off the femoral shaft, the intramedullary nail fracturing the femur below the nail or around the distal screws, and the lag screws bending or breaking. These failure modes are more directly influenced by the remaining variables, fracture reduction, fragment geometry and implant design.

2.4.3 Fracture Reduction

The overall strength of the implanted femora is a major consideration when assessing the total performance of any system. Several studies have been published comparing the strength of implants in cadaveric studies, when contrasting operative techniques have been used (Fig 2.10). When implanting any hip screw device the fracture must be realigned so the implant can provide support across the fracture site. The three surgical techniques most commonly used are anatomic reduction, medial displacement and valgus displacement osteotomies.

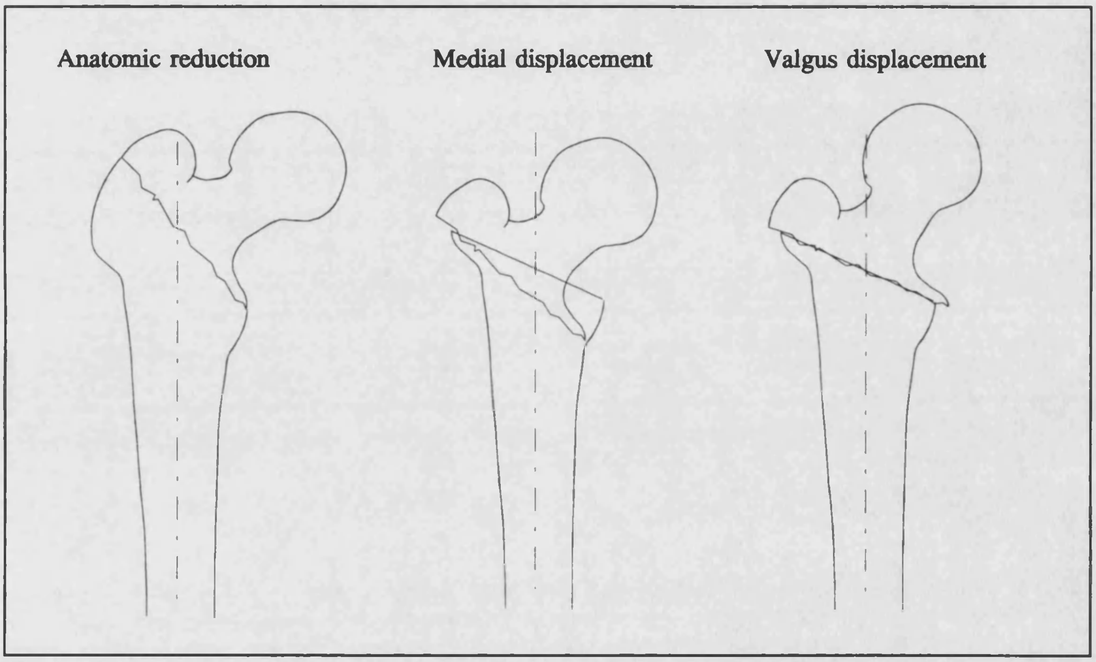

Fig 2.10 - Illustration of three fracture reduction techniques showing the repositioning of the femoral head.

Anatomic reduction returns the femoral head to its anatomically correct position. With a medial displacement osteotomy the head is displaced towards the central axis of the femur and with valgus displacement, the head is displaced away from the midline of the body. The latter two are both non anatomic repositioning of the femoral head and aid stability of the fracture.

Friedl *et al.* (1987) used 54 cadavers in their study, 18 with a 135° DHS and standard anatomic osteotomy, 18 with 150° DHS and a valgus osteotomy and 18 as a control. The difference in bone mineral density between each group was found to be insignificant. Half the specimens were tested under cyclic physiological loading and the other half with a non-physiological load. The valgus osteotomy was less successful in terms of deformation and maximum load capacity.

A further study by Friedl (1993) on 301 cadaveric femora involved a wider range of implants, including a range of fixed angle nail plates, intra- and extramedullary sliding devices and external fixators. The two sliding devices were found to have the greatest load bearing capacity under all loading conditions, the intramedullary nail proving to be the optimum implant for use with inter- and subtrochanteric fractures with all types of osteotomies. In both these studies there was a complex number of variables which once again makes direct comparisons between either technique or implant very unreliable and difficult.

Sonsteguard *et al.* (1974) performed a study to establish the compression strength of a four part fracture comparing anatomic reduction with medial displacement. The implants included two different fixed angle nail plates and a sliding hip screw. The specimens were loaded at 13mm/min until failure of the construct occurred. The authors concluded that biomechanical strength was less affected by the reduction technique used, than by the choice of implant. This conclusion was also reached by Kaufer *et al.* (1974) in a similar study comparing anatomical reduction, medial displacement and a lateral displacement with three alternative implants.

A more direct comparison of reduction techniques was completed by Chang *et al.* (1987) using only one type of implant to establish the optimum load transfer between the implant and the bone across the fracture site. Eighteen pairs of femora were fractured into 4 parts and implanted with a 135° sliding hip screw in either anatomic reduction or medial displacement. The proximal femur and implant plate were strain gauged to establish the load transfer between the two, while the femur was incrementally loaded. They concluded that anatomic reduction resulted in less tensile plate strain and a higher calcar strain in the femur. This suggested that the implant would resist failure to higher loads and the fracture would heal at a faster rate, due to the compression forces transmitted. The greater load sharing potential with this structure would reduce the risk of implant fatigue.

2.4.4 Fragment Geometry

The overall stability of an anatomically reduced unstable four part fracture is largely dependent on the fragment geometry, that is the number of parts making up the fracture and the size and placement of each part. Apel *et al.* (1989) looked at unstable fractures with a large or small posteromedial fragment, fixed with a number of implants. The fractures were all anatomically reduced and loaded at a rate of 10mm/min until failure occurred. All implants were able to resist failure to a greater load with large fragments present, clearly indicating that stability provided by the surgeon during surgery is vital for any fixation device. To bring the argument around full circle, Walsh *et al.* (1990) considered the reduction technique, the bone quality and the position of the lag screw within the head in their cadaveric study. The protocol involved cyclic loading of the implanted cadavers at 5mm/min to set multiples of body weight. They stated that the reduction technique had an effect on the failure mode but that it was the placement of the lag screw which still proved to be the most influential factor in the overall failure mechanism.

2.4.5 Implant Design

A simple biomechanical study by Jensen *et al.* (1980) examined implants under static conditions to determine the load at which yield occurred. This study compared a sliding hip screw with the Jewett Nail Plate and the Mclaughlin implant. As Kyle *et al.* (1980) indicated that the lag screws were prone to jamming, in this study the sliding lag screw was glued into the barrel to derive a better comparison with the fixed implants. The sliding hip screw proved to be the strongest implant by resisting failure due to lag screw bending, the 135° plate performing better than the 150° plate. This study indicated that using a high angled nail that would increase the sliding performance, would also increase the risk of the implant itself failing.

Fracture of the implant itself has been reported in clinical trials, either early post-operative or as a result of fatigue at a later post-operative stage. The majority of the biomechanical studies mentioned have all examined the overall strength of the implant/femur construct under monotonic loading conditions. However, under this type of loading the cyclic nature of physiological loading is not represented. Subsequently a number of studies have been performed to establish the fixation strength of sliding hip screw devices over other devices in cadaveric studies, using a more physiological load cycle. Larsson *et al.* (1987) completed static and cyclic tests on a range of implants in cadaveric tests. The static test consisted of the application of an incremental load. The elastic deformation was measured in three planes at each step and the stiffness was calculated. The cyclic load was applied by a three axis hip joint simulator specifically designed for these tests, applying a complex double peaked load cycle. This study showed that the strength of the femora was significantly greater when subjected to cyclic loading due to the viscoelastic properties of bone (section 2.1.2).

Clark *et al.* (1990) compared the 135° and 150° sliding hip screws and three cortical lag screws. A non-physiological cyclic load of three times body weight was applied to the femoral head at a rate of 0.5Hz and the displacement of the fracture examined. The bone quality for each femora was measured prior to testing. They concluded that no superior fixation was derived from the sliding screws and that the bone quality was the most significant factor. Larsson *et al.* (1988) completed a similar study between a nail plate and two different designs of sliding screw. The load cycle was again the more complex walking pattern with a double peak and each implanted cadaveric bone was subjected to 20,000 cycles. In this study the sliding devices clearly performed better in resisting displacement of the fracture and hence shear and plastic deformation. Curtis *et al.* (1994) compared an intramedullary device with a sliding screw, loading the test specimens with a sine wave form at 1Hz. The intramedullary nail exhibited a superior rigidity of fixation over the hip screw device, although the final number of cycles to failure was similar. From these three studies, despite the use of the physiological loading, the outcomes were contradictory, largely due to the range of different test protocols employed and the number of variables examined by each group of authors. This highlights the need for a standardised testing protocol for hip fracture implants, allowing a comparison to be made between different studies.

To examine the failure modes of different devices, Kreusch-Brinker *et al.* (1993) loaded cadaveric bones implanted with an intramedullary sliding nail, a DHS and blade plate, cyclically and under a single load to failure. Both loading regimes lead to the same failure mode for each implant; lag screw cut-out for the two 'extramedullary' devices and fracture of the femoral shaft with the intramedullary nail. The intramedullary nail withstood more loading cycles to failure for both per- and subtrochanteric fractures. The results from this study predetermined the end point for all the testing as failure, enabling a comparison to be made between the failures for the contrasting loading regimes.

As an overall comparison of a wide range of implants, Tencer *et al.* (1984) compared seven different implants in a range of cadaveric tests. These included angle blade plates, intramedullary nails and sliding hip screws, along with other less commonly used implants. Tests were carried out in isolated torsion, bending, tension and compression, with varying degrees of success. The intramedullary devices were found to be the stiffest in bending and in combined bending and compression to failure and they were able to support twice the load of the plate systems. The study recommended the use of intramedullary systems for the fixation of unstable fractures, in comparison to stable fractures with improved bone contact where the plate systems were thought to be more appropriate. A study by Gurtler *et al.* (1986) undertook a comparison of four implants including a sliding hip screw, in cadaveric test sequences. In contrast to the previous study, they concluded that the sliding hip screw was a stronger implant, when used with both stable and unstable fracture configurations. Once again the contradiction between these studies was probably due to the complexity of the studies themselves. No significance could be obtained from the results due to the large number of variables and the small number within each statistical group.

A smaller study between sliding hip screws and parallel cannulated screws, under isolated axial loading, lateral bending and torsion, was completed by Blair *et al.* (1994). They recommended the sliding devices primarily due to their displacement ability, as significant rigidity was not apparent with the multiple screw system. Swiontkowski *et al.* (1987) employed a more complex cyclic bending test along with a torsion test to establish the optimum number of cannulated screws when compared to the DHS. They stated that under bending the implants were comparable but that the DHS provided relatively little torsional stability. Finally, Goodman *et al.* (1992) compared a DHS with the system of three pins, strain gauging the femora and loading the femur in isolated compression and torsion. They used six paired femora and simply stated that there was no significant differences between the two systems for compressive or torsional loading using their model.

Both intra- and extramedullary sliding hip devices have the ability to allow impaction of the bone across the fracture site, resulting in redistribution of the load between the implant and the bone. To investigate the load transfer between the implants and the bone, the strain induced in the two devices during the loading regime has been examined using strain gauge techniques.

Jacobs *et al.* (1980) used six paired cadaveric femora, with a single saw cut fracture, to compare a sliding hip screw with a one piece nail plate. The proximal femora and the implants were both strain gauged to allow loading to be assessed. The femora were statically loaded at a constant rate until failure occurred. Both devices finally failed due to cutting-out of the femoral head, but the hip screw experienced less bending force and a greater tension. By acting as a 'tension band' the authors felt it transmitted the load to the femur more successfully, reducing the bending arm as the sliding screw reduced in length. This result supported the mathematical theory developed by Gill *et al.* (1989).

Fracture of the femur post-operatively has been identified as a failure mode, particularly with the intramedullary nail, although it has also been reported in trials with the sliding hip screw. One theory on how to reduce the risk of this particular failure, is to match the implant angle to the anatomic angle of the femoral neck, hence reducing stress in the implant and femur. Meislin *et al.* (1989) investigated the influence of the plate angle of a sliding hip screw, on stress in both the device and the proximal femur. The plate strain appeared to be greatest for the lower angle devices. The femoral strain reduced as the fracture was made more unstable and less load was transmitted across the fracture site. It was noted that sliding was greatest with the higher angled plates despite the reduced load transfer. They concluded however, that the argument for using the plate angle closest to the biomechanical axis of the hip is overstated and that plate angles could be standardised.

This once again highlights the results recorded by Kyle *et al.* (1980) and Jenson *et al.* (1980) with regard to which optimum implant angle to use. Kyle recommended a greater angle to enable lag screw sliding to occur whereas Jensen recommended a smaller angle to improve the yield properties leading to lag screw bending. The latter study tested a range of implants with equal bending arms. Under these conditions the lower angles devices had shorter lag screw lengths, eliminating the expected reduction in strength compared to the high angle devices. Without an accurate standard test to compare the angles in a realistic physiological biomechanical test, the results from clinical trials comparing the implant angles would need to be considered to reach any firm conclusion.

The intramedullary nail is designed to have mechanical advantages over the external plate due to its shorter lever arm, from its medially placed positioning and lower bending moment (Fig 2.11). In a related study completed on the intramedullary nails, Rosenblum *et al.* (1992) continued their study of stress within the femur with both stable and unstable fractures. Ten pairs of femora were tested, five with distal locking screws and five without. The nail was found to transmit more load to the calcar region as the fracture became more unstable, in contrast to the sliding plate results of Meislin *et al.* (1989) and an earlier study by Rosenblum *et al.* (1992). The load transfer was similar in pattern to that exhibited by a hip replacement prosthesis. Due to the stiffer intramedullary implant, the load was transmitted further down the femora and was not significantly altered by the use of distal locking screws.

Shaw *et al.* (1993) undertook a comparative study between a sliding hip screw and an intramedullary nail on 18 paired femora, for a range of fracture patterns. They concluded that with unstable fracture patterns the two implants performed equally, but felt that the sliding hip screw allowed greater fracture stability.

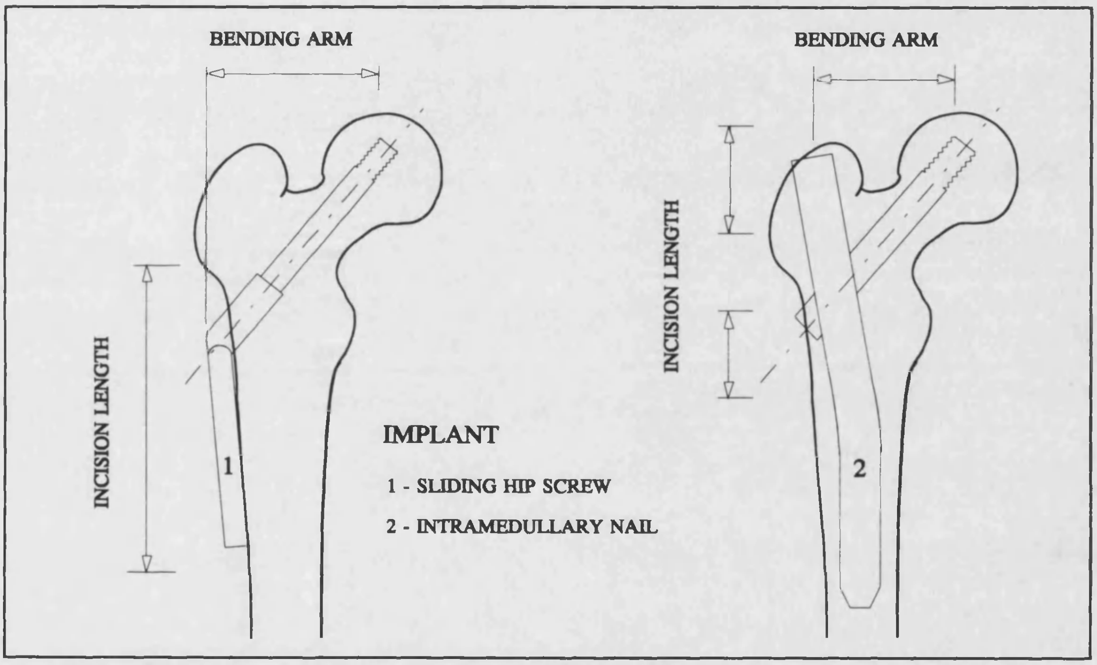

Fig 2.11 - The bending moments associated with the lateral plate and the intramedullary nail.

The external device overcame the problem of cantilevered loading on the locking screws of the intramedullary device, which could lead to the femur fracturing distally. Mahomed et al. (1990 & 1994) directly compared the rigidity of implanted cadaveric femora with the strain patterns induced in the femur due to an extra- and intramedullary sliding implant. The failure loads for the two implants were comparable in subtrochanteric fractures but the intramedullary nail appeared to be superior in the intertrochanteric fracture situation, transmitting more medial load to the femur.

2.5 Clinical Studies in Hip Fracture Fixation

Sliding hip screws have become an established implant for fracture fixation of intertrochanteric fractures. However, they still create a great deal of interest in clinical literature as well as the biomechanical literature due to the range of other contemporary implants available, indicated in the preceding biomechanical studies of implant performance (section 2.4) and the relatively high failure rates which still exist. As the incidence of femoral fractures increases, the demand for internal fixation also increases and the requirements for a consistently high success rate become more important.

The introduction of new implants will increasingly become more restricted with new controls being introduced by the European regulatory authority. Surgeons must establish which is the best implant for a particular fracture, a procedure that is more commonly decided through clinical trials rather than scientific biomechanical analysis. However, as the regulations tighten, the requirement for pre-clinical testing will increase, before controlled clinical trials can take place. To determine what testing must take place on new implants, a complete understanding of the clinical performance of current implants is therefore required.

2.5.1 The Dynamic Hip Screw (DHS)

Poigenfurst *et al.* (1983) undertook a study replacing their usual internal techniques with the DHS, for all femoral fractures. For stable intertrochanteric fractures they had previously used Enders Nails and for unstable fractures (Pauwels' III) they used four cancellous bone screws. They reported the results from 30 cases in this study and suggested that the DHS was a more successful implant for both fracture groups.

The number of reported failures for the DHS varies considerably, although the failure modes themselves remain consistent. Paschke *et al.* (1991) reported no failures in their study of 179 cases considering of a range of fracture configurations. In comparison, Hersche *et al.* (1989) reported that the DHS was an unsuitable implant for use in cases of four part fractures from their trial of 65 cases, with 14% of patients classified as failures due to leg shortening of more than 10mm, caused by lateralisation of the greater trochanter. An acceptable level of leg shortening is reported to be around 2mm (Harper (1982)). A large trial of 1871 patients undertaken in Belgium throughout 32 hospitals suggested an overall failure rate of 3.6% for the DHS (Putz *et al.* (1990)). When the patients were subdivided into stable or unstable fractures, within the unstable fracture group the failure rate increased to 6.6%. These three studies indicated the variation in published literature, in terms of both the trial size and reported outcomes. Larger trials would inevitably produce more statistically significant results, but if an implant produced too many failures after a small number of cases, ethics must determine whether the numbers should be increased for the sake of publication.

The operation to implant a DHS is generally considered to be a relatively simple procedure and as such is often one of the first operations a young orthopaedic registrar will perform. Osterwalder *et al.* (1985) reported 54 DHS cases, of which six cases had to be re-operated, four due to technical faults introduced during the initial operative procedure. Ortner *et al.* (1989) reported two incidences of technical mistakes in the operative procedure from a larger trial of 509 patients. The authors also reported two cases of the DHS breaking. This implant failure was also reported by Kwansy *et al.* (1991) as the sole failure mode in three out of 77 cases followed up post operatively.

The two most common failure modes reported for the DHS are the lateral plate pulling off the femoral shaft or the lag screw cutting-out of the femoral head. A clinical explanation for the lateral plate failure is the inability of osteoporotic bone to provide enough support for the implant under load bearing conditions (Denton (1976)). Sperner *et al.* (1989) reported three cases of the lateral plate pulling-off from a study of 198 cases with an average age of 74.4 years. Jensen *et al.* (1978), Siebler *et al.* (1987) and Larsson *et al.* (1988) all reported cases of lag screw cut-out in their trials, ranging from 5.3% to 2.5%. The former two trials were relatively small, examining only unstable fracture conditions, but the latter was a large trial of 607 cases including all fracture configurations. No other failure modes were recorded in any of these three studies.

Several explanations have been reported for cut-out failure of the lag screw. Mainds *et al.* (1989) reported nine cases of cut-out from a study of 385 patients. The only significant variable they attributed to these failures was the position of the lag screw in the superior half of the femoral head. They recommended placing the screws in a central or poster-inferior position within the femoral head. This was supported in a similar clinical study by Thomas (1990) in which 87 operations were performed with nine cases of screw cut-out recorded. They concluded that failure could occur with any fracture reduction technique if the lag screw was poorly placed. These studies both compliment the biomechanical studies which investigated screw placement.

Wu *et al.* (1991) were more concerned with the distance of the screw tip from the cortical bone as an indicator of failure, suggesting an optimum distance of 10mm, the distance recommended by the implant manufacturers. Mullholland *et al.* (1972) reviewed 80 X-rays retrospectively before starting their trial. From the review they predetermined the requirement for the screw position to be central in the femoral head with a 'deep' penetration. Despite their initial research they still reported four cases of lag screw cut-out in their trial of 89 patients.

Nue-Moller *et al.* (1985) undertook a prospective study of 104 patients, including stable and unstable fracture configurations. They reported eight cases of failure due to lag screw cut-out. Five of these failures were directly attributed to the poor quality of the osteoporotic bone. In the remaining three, the lag screw failed to slide, which in turn lead to penetration of the femoral head. Simpson *et al.* (1989) investigated the failure mechanisms in a review of 223 cases. They reported a rate of 17.5% cut-out failure, 4% lateral plate pull off and less than 1% implant breakage. They suggested that 'jamming' of the lag screw was the significant factor in all the failure modes, causing the implant to act as a one piece device with the resulting associated failure modes.

A recent study by Nakata *et al.* (1993) investigated the amount of sliding of lag screws *in vivo* in relation to the healing time, for a range of fractures. The authors found a significant correlation between the amount of sliding at 2 weeks postoperative and the time to fracture healing. Where a total movement of over 7mm was detected the time to fracture healing was shortest. In a retrospective study by Rha *et al.* (1993), excessive sliding of the lag screw was found in ten cases from a trial of 76, where 'excessive' was defined as 15mm or over (Steinberg *et al.* (1988)). In two cases this also resulted in cut-out of the femoral head, independent of the post-operative position of the lag screw within the femoral head. Excessive sliding was also considered to be a problem as a cause of delayed weight bearing in the patients, which could cause additional problems in the elderly patient group.

Yoshimini *et al.* (1993) summarised that controlled collapse of the fracture was advantageous in the recovery of all patients. In a retrospective study they found five cut-out failures from 47 cases. To overcome the problem of non-sliding they recommended using the maximum lag screw length, thereby facilitating a greater sliding capability. No advantage was established from using a greater implant angle, which had been suggested in a number of biomechanical studies. The bar chart (Fig 2.12) shows the variation in the most significant failure modes for the DHS from the failure rates reported in the clinical studies. The majority of the studies recorded screw cut-out as the major failure mode, bone quality or screw positioning reported as the most likely cause.

A number of case studies have been published examining the specific failures associated with sliding hip screws. These failures ranged from lag screw cut-out to the more unusual secondary fractures and implant breakages. Three cases of cut-out failure were highlighted in a paper by Doherty *et al.* (1979). They isolated one stable fracture configurations and two unstable fractures where the lag screw had penetrated the femoral head between 4 and 6 weeks post-operatively.

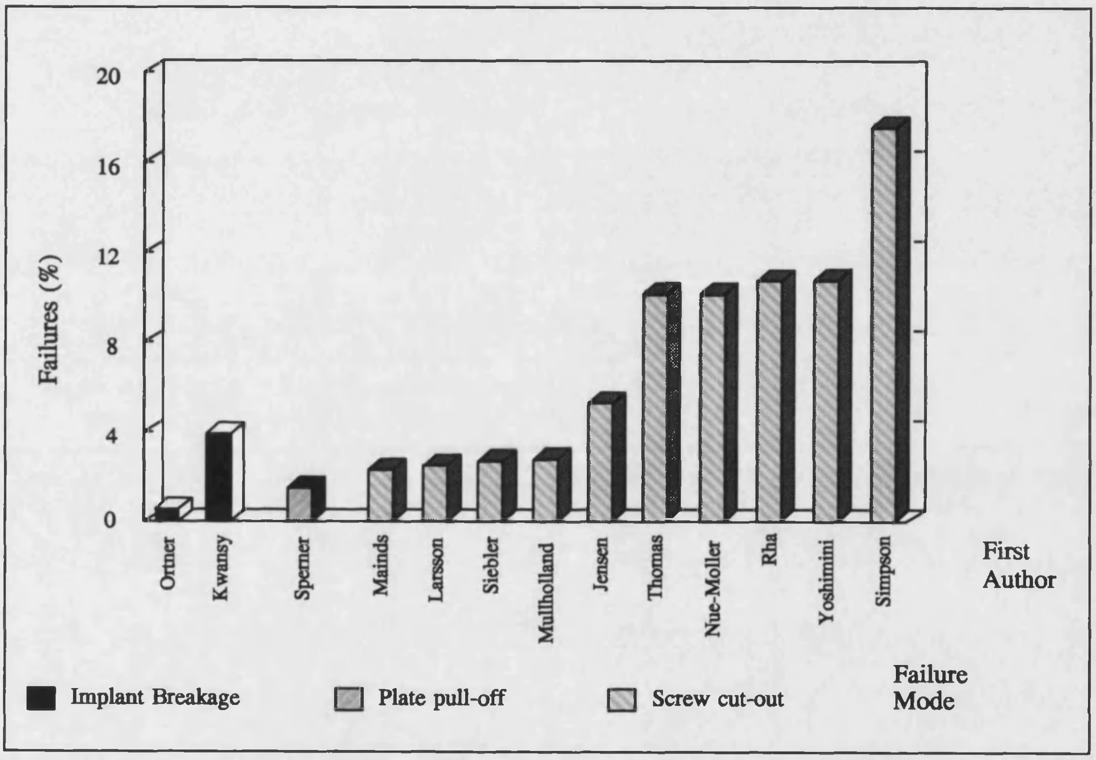

Fig 2.12 - Bar chart showing the range of values for the most significant failure modes of the DHS in clinical studies.

In each of the cases, the lag screw had been poorly positioned within the femoral head per-operatively, then removed and reinserted along a second reamed hole. The authors estimated that the volume of the lag screw was approximately 10% of a femoral head volume. By reaming two cores out of the head the volume of bone removed made the procedure unstable, causing the resulting cut-out. Although insertion of the lag screw into the optimum screw position within the head and neck, is a major factor in the success of the treatment, removal and reinsertion of the lag screw was found to be highly detrimental.

DiMaio *et al.* (1992) reported on three cases of secondary stress-related fractures that occurred in association with the implant. The first case was the appearance of a linear transverse fracture extending down the lateral cortex of the femur 15 weeks after surgery for an undisplaced intertrochanteric fracture. This was attributed to the increased stress concentrations around the lag screw entry hole. The other two cases were subcapital fractures as a result of a non-union of the original intertrochanteric fracture. These fractures are classed as Young's Modulus fractures. They are thought to occur at the interface between the bone and metal, where there is an abrupt change in properties.

Jakobsen (1987) reported a case of breakage of the lag screw itself at the point of exit from the barrel 6 months post-operatively. On examination of the radiograph and lag screw it was concluded that the screw had jammed due to impingement with a second screw. The resulting bending force at the barrel had caused failure through metal fatigue. Marshall *et al.* (1993) reported a lag screw fracture that occurred 5 years post-operatively. The initial stable intertrochanteric fracture had healed, but on examination of the extracted implant, there appeared to be excessive galling of the barrel. This would have caused increased friction at the implant junction leading to jamming of the lag screw. Spivak *et al.* (1991) reported three cases where lag screw breakage had occurred. In each of these cases the problem was attributed to non-union of the initial fracture or a secondary fracture, causing the lag screw to fracture between 5 and 9 months post-operatively because of the excessive loads. The DHS implant was designed to provide initial stability for the hip as a load sharing device, with bony contact, not to provide long term stability supporting all the load.

Johanssen *et al.* (1995) and Rao *et al.* (1992) both reported cases of lag screw migration into the pelvis after penetration of the femoral head and acetabulum. In the first case, the bone quality was noted to be very osteoporotic and the lag screw was poorly positioned within the head. The patient fell after two weeks and the screw was located and removed. In the second case the screw placement was recorded as central, but the patient had a number of early falls post-operatively. After 4 weeks the lag screw was shown to have penetrated the acetabulum but after a delay of 1 week to surgery the lag screw had migrated so far into the pelvis it could not be retrieved. To prevent the lag screw becoming separated from the barrel, a compression screw can be inserted into the back of the lag screw to act as a locking mechanism. This screw was not used in either of these previous studies. To complete the reported failure case studies, in a paper by Hudson *et al.* (1992) two cases were reported where the compression screw had been inserted, but after 3 years and 18 months respectively, these screws had themselves come loose and migrated, one to the buttock region and the second to just above the knee.

2.5.2 Fracture Reduction

All surgeons have individual preferences and techniques when undertaking any operative procedure, with input towards the type of implant to be used and the reduction technique. The strengths of the different techniques was outlined in the biomechanical studies (section 2.4.3), with anatomic reduction shown to be the optimal mechanical solution.

Rao *et al.* (1983) performed 162 sliding hip screw procedures using anatomic reduction techniques (Fig 2.10). After weight bearing 90% of the fractures moved into medial displacement due to compression across the fracture site. The technique had the advantage of allowing early weight bearing with both stable and unstable fractures with only a 4% failure rate reported in the study. Nunn (1988) completed a study of the radiographs and case notes of 108 patients all treated by medial displacement osteotomies. In the group of unstable fractures around 40% failed due to cut-out, compared to the overall figure of 20% for the study. This difference was attributed to the lack of immediate fracture support with medial displacement, relying on the sliding ability of the lag screw to achieve delayed stability. This was not possible with unstable fractures due to the lack of medial support immediately post-operatively. A randomised study comparing anatomic reduction with medial displacement was undertaken by Desjardins *et al.* (1993). From 127 cases of unstable fractures, three cut-out failures occurred in each group. Medial displacement osteotomies were originally devised for use with one piece angle blade plates, to provide stability and prevent collapse or cut-out of the nail when weight bearing was commenced. As a result, the authors found that the procedure took significantly longer than the anatomic reduction with no clinical superiority.

To investigate the third operative reduction technique, Pun *et al.* (1987) fixed 70 unstable fracture configurations with valgus osteotomy, resulting in a failure rate of 8.6% due to screw cut-out. They compared this outcome to their previous technique of medial displacement and report the latter as having the greater success rate. Parker (1993) studied valgus osteotomies used for 663 cases with a 4.2% failure due to cut-out. The author concluded that the reduced bending arm achieved by the valgus positioning increased the stability of the fracture fixation, recommending its use over anatomic reduction. These two studies reached contradictory conclusions, which supported the theory that the surgical outcome was significantly influenced by surgical proficiency.

Clark *et al* (1990) treated 100 patients in a trial comparing anatomical reduction with valgus reduction. Valgus osteotomy was a simpler procedure with only one cut-out failure reported, compared to seven in the anatomic group. However the anatomic group had a greater chance of reaching their pre-injury walking capability, with a significantly shorter hospital stay. They concluded that despite the greater number of clinical failures, anatomic reduction produced a better long term outcome, particularly with unstable fractures.

Gargan *et al.* (1994) compared anatomic reduction with both valgus and medial displacement osteotomies. They found that the incidence of cut-out was increased with the two non-anatomic osteotomies. To establish a stable fracture realignment with the osteotomy techniques, the femoral neck length was shortened, reducing the available sliding length for the lag screw, leading to an increased risk of cut-out.

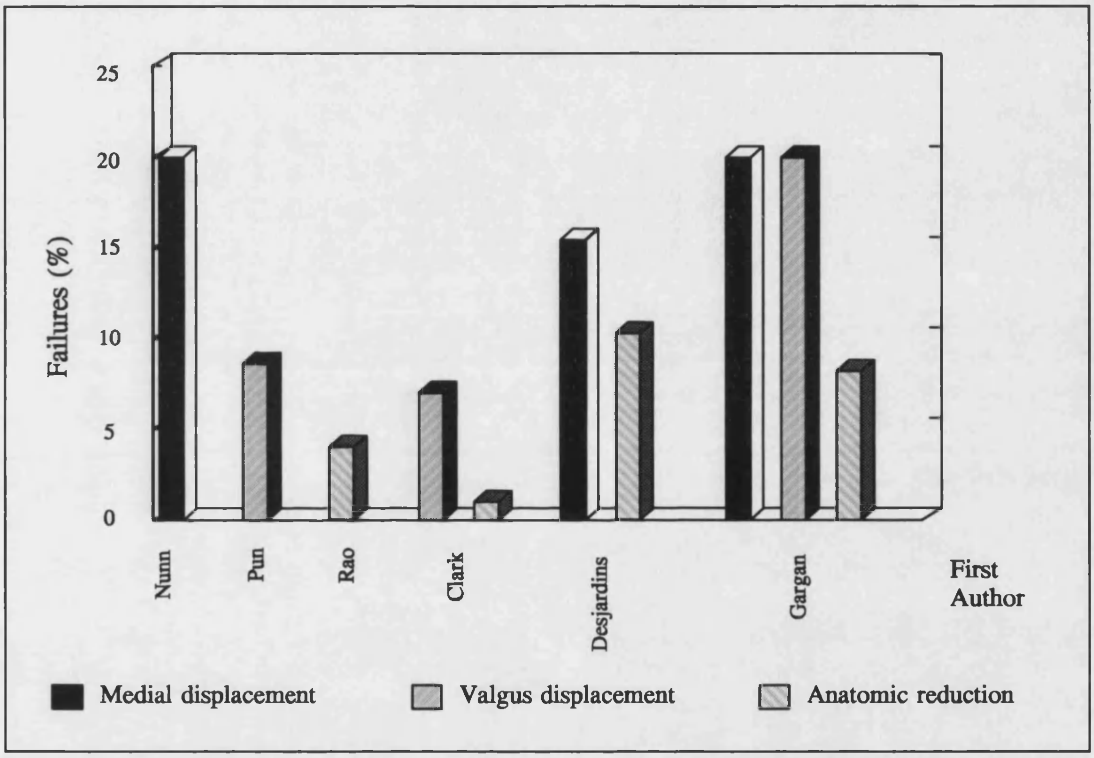

Fig 2.13 - Bar chart showing the percentage of failures of the DHS with alternative reduction techniques.

They concluded that anatomical reduction was the most appropriate technique in the majority of cases and care should be taken to ensure sufficient slide was available. From the studies examining reduction techniques, the bar chart (Fig 2.13) shows the variation in the failure results. From the three techniques compared, anatomic reduction appeared to provide the most reliable clinical results.

2.5.3 Implant Design

The sliding hip screw is gradually being used to replace other methods of internal femoral fracture fixation. One of these was Enders' Nails, long pins inserted up the femoral canal, extending the full length of the femur from the knee where they are inserted, to the femoral head. In direct comparative trials between Enders' Nails and the sliding hip screw, the latter is invariably recommended (Sernbo *et al.* (1988), Ludtke *et al.* (1991), Hontzsch *et al.* (1990)). Vescsei *et al.* (1995) suggested that in the hands of an experienced surgeon the Enders' technique could still be a useful implant in high risk cases.

A study of 77 stable and unstable cases by Rao *et al.* (1990), compared DHS and Enders' Nails. Failure modes of Enders' Nails included backing out, distal fractures of the femur, deformities due to external rotation and knee pain, with a higher incidence of reoperation. They recommended the DHS for use in all fracture configurations. The exception was cases of soft tissue damage or burns or in cases where blood transfusions have been refused on religious grounds. Barrios *et al.* (1993) published two papers on the outcome of 113 cases randomly assigned to the DHS or Enders' Nails. They directly related all the failures for both implants to the degree of osteoporosis. For unstable fractures with severely osteoporotic bone the failures were as high as 65% with the Enders' Nails and 50% with the DHS. From this they concluded that with high risk cases it did not matter which of the two implants were used. When the authors compared the post-operative walking ability of the complete range of patients, they found no difference in outcome between the stable and unstable groups or the type of implant used. The only significant determinant they found for restoration of pre- walking ability was the fracture reduction.

Bannister *et al.* (1990) undertook a randomised trial of 155 patients comparing the

Jewett Nail, a one piece nail plate, with the sliding screw system. They found the former resulted in more mechanical failure and a higher occurrence of reoperation. They did suggest that the implant itself had a minimal effect on the patient mortality or the overall success of patient rehabilitation, which was predetermined by the social dependence before fracture. Esser *et al.* (1986) reported 98 cases comparing the same two implants. They stated that the sliding screw system was a more complex operative procedure, leading to more operative difficulties from open reductions, but after 6 months this patient group were more mobile with better compression and fixation.

Jacobs *et al.* (1976, 1980) reported on 173 cases with failure rates of 21% for the Jewett Nail and only 6% for the DHS in their comparative trial, failures due to screw cut-out and resulting joint penetration occurring with both implants. Once again they reported that the hip screw required a more complicated operation but the average time in theatre was less. They recommended the sliding screw over the nail plate, resulting in good fixation and less clinical failures, with the prospect of early weight bearing. A significant rate of failure of the implant itself was reported by Pitsaer *et al.* (1993) in a comparative trial between the sliding hip screw and the McHaughlin Nail Plate, looking at unstable fractures only. They reported that 42% of the nail plates failed with a further 10% cut-out failures. In contrast to this the sliding hip screw cut-out in 18% of cases with no incidences of implant failure recorded. As a result they advised against the use of nail plates. All four of these trials reached the same overriding conclusion regarding a nail plate system, despite the different failure rates reported.

Several studies have compared sliding hip screws with Enders' Nails and nail plates (Kalsbeek (1991), Schmidt (1984) and Jensen *et al.* (1980)). In these comparative studies the sliding hip screw was invariably recommended over the other two implants, particularly in active patients. Enders' nailing was recommended over the fixed nail plates due to a lower incidence of non-unions. The series of 1071 unstable fracture cases reported by Jensen *et al.* (1980) compared the failure of the implant itself and incidences of cut-out. The plate system was significantly worse under both conditions (21% and 35%) compared to the Enders' Nail (0% and 16%) and the sliding screw (<1% and 6%). They clearly demonstrated that the sliding hip screw was that most suitable implant for unstable fracture configurations.

The Pugh Nail Plate is a sliding screw design with a tri-flanged nail in place of the threaded lag screw, as studied by Richards *et al.* (1990) in the biomechanical studies (section 2.4.1). McLaren *et al.* (1991) completed a trial of 100 patients to compare the two devices and found no significant difference in their performance, concluding that the Pugh Nail was a suitable alternative. Another fixation treatment that was examined in the biomechanical studies was the use of three slender pins placed into the femoral head in formation across the fracture site. Sorensen *et al.* (1992) compared the sliding hip screw to three Gouffon Pins. The failure rate for the pins in the early stages of the trial was found to be a startling 66%. The authors felt it necessary to terminate the study after 73 patients compared to the 260 they had initially planned. Obviously they did not recommend the treatment due to the excessive failure rate caused by the poor reduction achieved and the inaccurate screw placement which resulted in cut-out.

Davis *et al.* (1988, 1990) compared the DHS to the Kuntscher Y-Nail, an intramedullary non-sliding nail. They reported a failure rate in their trial of 230 patients of 14.9% for the DHS and 10.3% for the Kuntscher Nail due to cut-out. One implant failure was identified with both designs and 4% of the DHS pulled off the femoral shaft. On analysis of all these cases they concluded that cutting-out was more significantly affected by the position of the screw in the femoral head than the quality of the bone. Lag screws with their tip in the posterial region had the highest failure rate. The other significant factor was the fracture reduction performed per-operatively. The overall conclusion from this study was once again that the success of any device was dependent on the technical expertise of the surgeon. The mechanical advantage from the medial positioning of the Kuntscher Nail was balanced out by the lack of sliding of the lag screw.

2.5.4 The Gamma Nail

The DHS has been used successfully by a large number of surgeons in a variety of trials looking at a range of clinical aspects. The Gamma Nail by contrast is still not as widely used and requires a new operative technique. The number of trials completed using this system is far smaller with more variable results. With any new device, time is required to learn and become familiar with the techniques and this learning curve must be taken into consideration in any trial with a new implant.

Halder *et al.* (1992) completed a clinical trial on 123 patients with the Gamma Nail on both stable and unstable fractures. The semi-closed operative technique involved a shorter operation with less blood loss, with the importance of good operative technique stressed throughout the study. The reported failures in the study included two cases of screw cut-out and two shaft fractures below the tip of the nail. Forthomme *et al.* (1993) also stressed the importance of strict surgical technique in their study of 92 patients, in which they reported four cases of femoral shaft fracture per-operatively. A further three fractures occurred post-operatively with three additional cut-out failures.

Problems have been reported clinically in establishing the correct insertion point for the Gamma Nail. Poor positioning of the intramedullary nail leads to the nail itself touching the cortical bone at 3 positions, rather than the correct placement within the canal (Williams *et al.* (1992)). This would create stress risers within the cortical bone layer and possible shaft fracture. The ability to accurately insert the distal locking screws was reported to be a further problem. The learning curve for this implant should therefore be considered in any clinical study. In Williams' small study of 28 cases, nine cases of pre-operative difficulty were recorded, eight with the distal locking. This high proportion of problems was partially due to the seven different surgeons implanting the study cases for whom the level of experience must have been relatively limited, with no compensation for the learning curve.

Another small study of 29 patients by Lindsey *et al.* (1991), outlined results from the preliminary use of the Gamma Nail. The reported failures were two lag screws migrating within the femoral head and one femoral shaft fracture after a secondary fall. They also mentioned operative difficulty in inserting the distal locking screws in eight cases. The follow up of patients after 6 months indicated early weight bearing with excellent clinical results for all fracture configurations. Eberle *et al.* (1992) reported a trial of 50 cases of unstable fractures. These particular cases were the last 50 procedures completed in a larger series of 150, ensuring the surgeons had all learned the correct techniques required, with the result that the only failure reported was one post-operative shaft fracture. In contrast to this a recent study by DeLucas *et al.* (1995) looked at their first 52 cases, where six shaft fractures were reported.

The Gamma Nail itself was partially developed, in its early stages, by I. Kempf and A. Gross in Strasbourg. In a trial reported by Kempf *et al.* (1993) on 121 cases, the only failure mode they reported was lag screw cut-out in six cases. On analysis of the radiographs these were all found to be due to poorly positioned lag screws. Once again the experience of the surgeons in this trial resulted in a relatively small failure rate, with none of the shaft fractures that appear to be associated with its use.

Currently the largest trial completed on the Gamma Nail was by Boriani *et al.* (1991) in which 98 surgeons of a range of expertise, from 13 centres in Italy undertook 628 cases over a two year period. They concluded that the long term success of the device was very good and early weight bearing was encouraged, but that the device was prone to surgical error. Nine fractures of the femoral shaft occurred per-operatively due to surgeons hammering the nail down the shaft, a technique strongly criticized by the manufacturers. Forty cases of the distal screw missing the nail were reported, which was discovered to be due to problems with the aligning equipment itself. All the failures occurred early in the trial and were highlighted and then rectified in the later procedures, considering the learning curve as the trial progressed. Seven cases of screw cut-out were reported in the trial, all due to poor screw position. They also reported five cases of femoral fracture post-operatively, four of which were due to a secondary fall.

Two studies have been published that report cases of the Gamma Nail itself fracturing, a failure that was surprising because of the material strength and the implant design. Megas *et al.* (1995) found one case of the intramedullary nail breakage in a trial of 80 cases. This was simply replaced with an identical nail and the fracture healed successfully. They also reported three pre-operative shaft fractures and two cases of lag screw cut-out. Verberg *et al.* (1995) recorded one nail fracture from 156 cases which were performed by 36 different surgeons, with almost 30% of the operations supervised by two traumatologists. The other failures they recorded included thirteen cases of lag screw cut-out and seven shaft fractures.

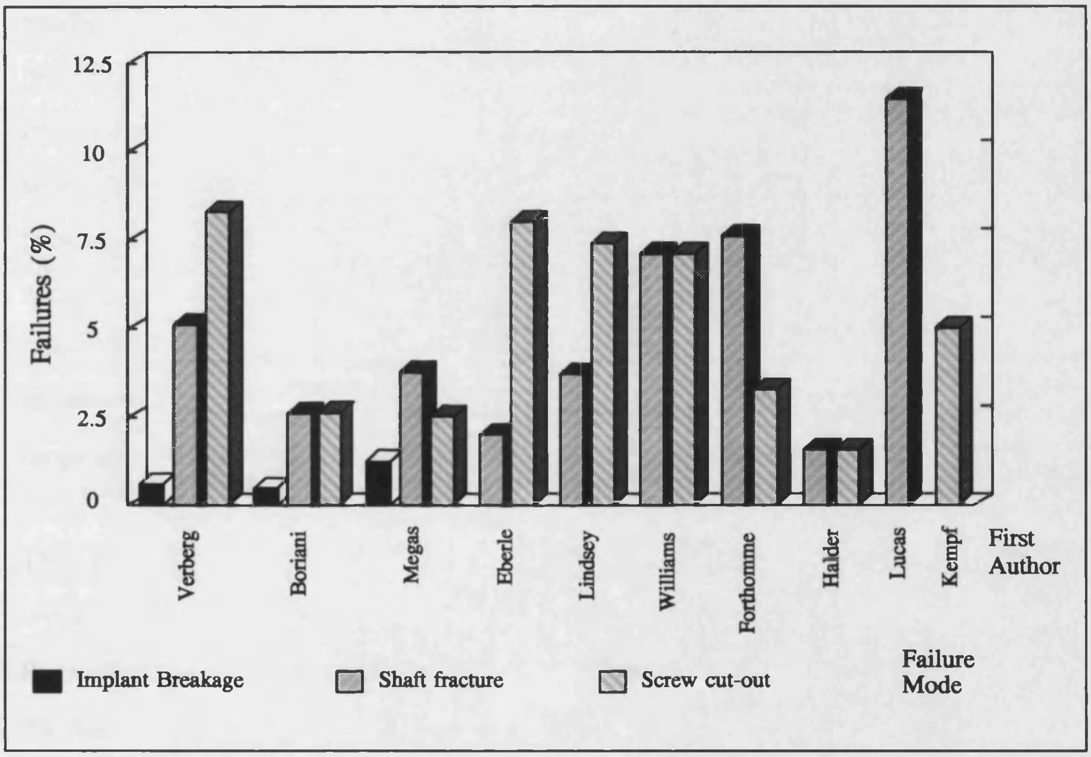

Fig 2.14 - Bar chart showing the range of values for failure of the Gamma Nail in clinical studies.

Interestingly 61% of the failures occurred in the first half of the trial and the number of failures resulting from the supervised cases was relatively low.

Comparing all the failure rates from the range of clinical studies investigating the performance of the Gamma Nail, the larger trials appeared to result in the lowest failure rates (Fig 2.14), particularly for fracture of the femoral shaft. The large trial size accommodated the learning curve for the Gamma Nail in the failures recorded.

Case reports of specific failures of Gamma Nail have also been published. The failure mode of primary concern was fracture of the femoral shaft due to the nail itself, either per- or post-operatively. This is not a failure identified with any other type of internal intertrochanteric fracture fixation. Mahaisavariya *et al.* (1992) reported three cases where the femoral shaft had cracked around the distal screw holes during the operative procedure, two of the cases in young men who had been admitted after traffic accidents. The holes were initiated by hammering a pointed trochar into the cortical bone layer to perforate the bone prior to drilling. It was suggested that the presence of the nail inside the femoral canal created hoop stress in the cortical bone and tapping of the bone whilst preloaded resulted in shaft fractures.

This protocol was not recommended in the latest version of the operative procedure, replaced by predrilling with a smaller diameter drill bit (Lacroix *et al.* (1995)). Pagnani *et al.* (1994) reported a case of a subtrochanteric fracture that occurred around the nail post-operatively after a fall at 1 week. Distal locking screws had not been used in this case and the fracture appeared to be a spiral fracture, induced by torsional instability from the lack of distal locking.

Van den Brink *et al.* (1994) highlighted four cases of failure of the implant itself. In each case the intramedullary nail had failed around the lag screw hole, after an average time of 11 months. In two of the cases the patients had cancer which resulted in delayed fracture healing. The other two cases were subtrochanteric fractures where weight bearing was delayed post-operatively due to instability. The four cases reported were taken in isolation from a patient group of 2500 cases. They concluded that in cases of delayed nonunion where full weight bearing is typically being undertaken the metal could fail through fatigue. With reference to the case study looking at fatigue failures of the DHS by Spivak *et al.* (1991), the mean time to failure was longer for the Gamma Nail.

2.5.5 The DHS Versus the Gamma Nail

A number of clinical trials directly comparing the DHS with the Gamma Nail have recently been published. A prospective randomised trial of 100 cases by Guyer *et al.* (1991) concluded that the Gamma Nail allowed better early weight bearing than the DHS and that the operative times, blood loss and hospitalisation were comparable. Three cut-out failures were recorded for the DHS. For the Gamma Nail one cut-out failure and one additional pre-operative femoral fracture were reported. In total six DHS had to be reoperated and five Gamma Nails, the remainder due to soft tissue damage. The use of the Gamma Nail for unstable fractures was recommended, with regard to the high percentage of early weight bearing leading to more successful rehabilitation of the patient.

Aune *et al.* (1994) included 378 cases of both inter and subtrochanteric fractures in their study. They reported a failure rate of 7% for the Gamma Nail and 1% for the DHS. The majority of Gamma Nail failures were due to shaft fracture (6%) and of these, half occurred per-operatively caused by introducing the nail into the femoral shaft with a hammer. The surgical protocol states that the femoral canal should be reamed to a size large enough to introduce the nail by hand. The other shaft fractures occurred on average 2 months post-operative due to additional minor trauma. The remaining Gamma Nail failure and all the DHS failures were due to lag screw cut-out which could all be related to poor positioning within the femoral head at the time of surgery.

Bridle *et al.* (1991) also stated that operative time, blood loss, wound complication, hospital stay and patient mobility at follow up were all comparable for the Gamma Nail and DHS, in their randomised study of 100 patients. Three cut-out failures were reported for the DHS and two for the Gamma Nail, which also had four femoral fractures post-operatively. The new techniques required with the Gamma Nail prevented this study recommending its regular use except with high subtrochanteric fractures, where its success rate was far superior to the DHS. O'Brien *et al.* (1993)

also reported advantage in the routine use of the Gamma Nail over the standard DHS from their study of 102 intertrochanteric cases, looking at the operative constraints. They reported two DHS failures compared to seven Gamma Nails, which included two per-operative fractures and one post-operative. The similarity between surgical time and blood loss between the two techniques was surprising in both these studies. The closed technique used for the Gamma Nail should help prevent blood loss and reduce operative time, but the unfamiliarity reduced the surgical advantages.

A larger study of 200 patients by Radford *et al.* (1993) reported a lower blood loss for the Gamma Nail than the DHS. They also reported eleven femoral fractures with the Gamma Nail, five post-operative, and one with the DHS due to an unrecognised subtrochanteric fracture at the time of surgery. The screw cut-out failures were three DHS and one Gamma Nail, all attributed to poor positioning. They concluded from this study that the Gamma Nail was an unsuitable implant due to the problems of positioning the nail within the femoral shaft resulting in the high frequency of shaft fractures. Eckland *et al.* (1993) included 378 patients in their trial. They found ten cases of failure of the Gamma Nail failure due to shaft fracture, of which half were due to technical errors per-operatively. One DHS cut-out was recorded compared to three Gamma Nail. The results for this trial were very similar to the previous one, but the authors made no recommendations in their conclusions.

In response to these studies, a trial by Hogh *et al.* (1993) of 299 cases concluded that despite the higher incidence of femoral fractures with the Gamma Nail, it provided an improved long term prognosis. They experienced eight femoral shaft fractures and ten cut-out failures compared to only six cut-outs with the DHS. They suggested that the Gamma Nail was a more demanding operation than the DHS. Goldhagen *et al.* (1993 & 1994) reported earlier weight bearing and quicker rehabilitation with the Gamma Nail, specifically with subtrochanteric fractures where improved axial and rotational stability was observed. They included 75 cases with no failures of the DHS, two Gamma Nail cut-out failures, one shaft fracture and one case of missed distal locking.

Leung *et al.* (1992) outlined the potential advantages of the Gamma Nail over the DHS, from 186 fractures randomly treated, with less surgical trauma, less screening time, less blood loss and earlier rehabilitation.

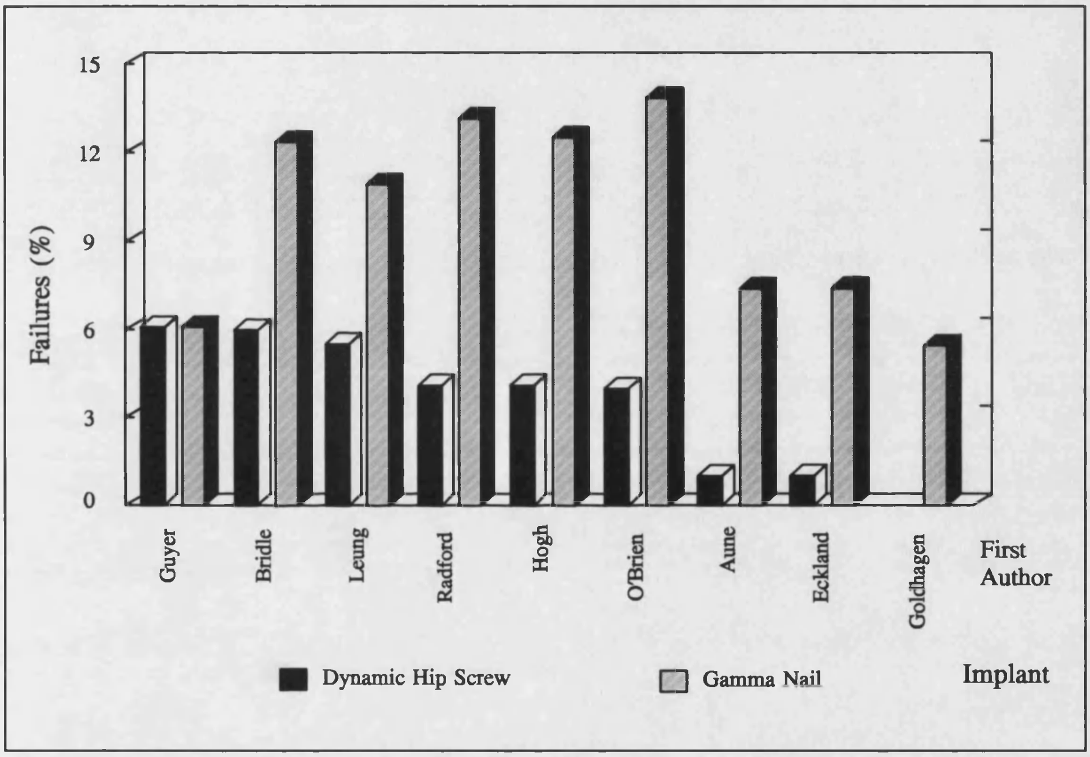

Fig 2.15 - Bar chart indicating the different failure rates of the Gamma Nail and the DHS in comparative clinical studies.

They reported two post-operative femoral fractures after 3 months with the Gamma Nail and two cases of lag screw cut-out compared to three with the DHS. The patient group within this study were Chinese and the authors felt additional problems were introduced due to the small femora. However with the use of a modified nail with accurate surgical technique, the ease of implantation and early weight bearing with even the most complex fractures, outweighed any disadvantages.

By comparing the clinical failures reported from the comparative studies between the Gamma Nail and the DHS (Fig 2.15), the DHS appeared to be the more reliable implant. The larger trials do, however result in a smaller percentage difference between the failure rates. The learning curve problems experienced with any new implant or operative procedure should not be overlooked in when considering these results.

2.6 Findings Obtained from the Literature Review

It has been shown in the review of the current literature that there are contradictions and complications in both the clinical and the biomechanical analysis of sliding hip screws. The biomechanical literature is confusing due to the wide variety of test methodologies and related results, making direct comparisons or conclusions impossible. An understanding of the problems associated with the clinical performance is essential when undertaking a study of these devices, in terms of implant failure and possible causes. This will allow an insight into the appropriate test methodology to be gained.

The literature identified five variables which could effect the outcome of a sliding hip screw operation: *i*) bone quality, *ii*) implant placement, *iii*) fragment geometry, *iv*) fracture reduction and *v*) implant design. Each variable was shown to have some influence on the success of hip fracture treatment under biomechanical analysis.

i) The quality of the bone influenced the type of treatment that should be used, as poor quality bone increased the risk of lag screw cut-out.

To translate this information to the clinical situation, a simple assessment technique would be required prior to surgery to allow the surgeon to determine the optimum treatment. In many surgical centres, the choice of treatment for all hip fractures is predetermined on a financial basis, the cost required to maintain a range of different implant systems being too great.

ii) Poor placement of the implant *in vivo* was found to increase the risk of cut-out.

The implant placement itself is essentially dependent on the experience and expertise of the operating clinician, influenced by the fragment geometry of the fracture itself and the fracture reduction used to realign it.

iii) The fragment geometry is a result of the type of injury and the more complex fractures, resulting from impact injuries and serious falls, could lead to stability problems and high stresses in the implant and bone.

The fragment geometry directly influences the fracture reduction technique employed by the operating surgeon.

iv) The reduction technique influences the stability of the realigned fracture, the anatomical alignment of any fracture providing the best support and load distribution for a stable union.

Of the factors under the surgeons control, the placement of the lag screw was established to be the most important variable.

The remaining variable is implant design and from the biomechanical studies reviewed, the range of test protocols and influential parameters were too great to establish an optimum solution. In an attempt to effectively compare different implants, the testing itself must be scrutinised and carefully considered by engineers and clinicians, to determine what are the most important parameters and how to examine them.

All the biomechanical studies reviewed were conducted under either static or cyclic loading patterns. In the case of the static loading, the loads have either been applied incrementally or at a constant rate. The increments and loading rates applied in each study varied considerably, with no particular standard and the angles at which the femora were mounted in the testing machines also varied between studies. Static loading implies that the femur itself is not moving and hence the situation represented is that of a single or double leg stance position with no movement of the patient.

In many cases the biomechanical results recorded contradict the clinical results being achieved on a regular basis. The loading regimes have not represented *in vivo* conditions, which would require cyclic loading to overcome the viscoelastic properties of the bone in cadaveric studies or some form of movement cycle to represent the postoperative conditions experienced by the implants themselves.

From the clinical literature, the DHS was consistently reported to be a superior implant when compared with non sliding implants such as Enders' Nails or one piece nail plates, the more traditional system that it replaced. The most commonly reported failure for the DHS was lag screw cut-out, with rates ranging from 2% to over 17% of the trial patients. Other failures were cases of the implant itself breaking, usually where the fracture had not healed successfully and the consistently high loads experienced by the implant resulted in fatigue failure, or the lateral plate pulling off the proximal femur. All of these failure modes could be related to the quality of the bone into which the implants were placed and the positioning of the implant in situ.

The reduction techniques were compared in clinical studies to establish which was the optimum procedure. Once again the anatomic reduction appeared to be the best solution when considering overall stability of the fracture, but it was not the easiest procedure to perform. Contradictory results were reported in the literature by different surgical teams, the outcome of the operative procedures strongly influenced by the level of expertise using a particular system. A team of engineers at Loughborough University have proposed a vision guided robotic system as a solution to overcoming surgical variations, (Bouazza-Marouf *et al.* (1995)) but there is a large step between theory and practice.

For the intramedullary Gamma Nail, the most commonly reported failure mode in the literature was again lag screw cut-out, between 2% and 8%, with a second failure mode of femoral shaft fracture, between 2 and 11%. There were also cases of implant breakage due to metal fatigue. A number of studies compared the DHS and the Gamma Nail clinically with a variety of recommendations. Despite a consistently higher failure rate with the intramedullary nail, some authors felt that it was a suitable replacement for the sliding plate system. Much of the variation between the reported results was due to learning curve problems, the more commonly used DHS providing better outcomes due to the greater level of expertise with this implant over the newer designs.

Clinical trials must be carefully designed to overcome any bias in terms of experience of the clinical staff or within the patient groups. If this is done, the outcome of the trial will represent the population and the conclusions can be used as a source of reference. As the need for more accurate biomechanical, pre-clinical analysis of implants increases, the findings from current clinical literature becomes more important. A full understanding of the *in vivo* performance of sliding implants is required if a realistic test is to be established to recreate clinical conditions.

Chapter 3

CADAVERIC STATIC STUDY

A study has been undertaken to recreate the failure modes reported in the clinical literature under laboratory conditions, to establish the failure loads associated with the Gamma Nail and the DHS. This involved testing cadaveric femora under simple static loading conditions until failure of the implant or bone occurred. To maximise the use of cadaveric tissue within the study, it was proposed to develop a test protocol which allowed three individual test sections to be obtained from each femora.

A number of biomechanical studies have been reported that test sliding implants to failure in cadaveric testing (section 2.4), recording the failure mode and related load. However, no previously reported studies have used three comparable test configurations from each femur, allowing a direct comparison to be made between the failure loads for different failure modes. In this way the assumption that the most common clinical failure of lag screw cut-out is the most likely failure mode, can be tested by isolating the femoral heads from the shafts and establishing which failure mode was associated with the lowest failure load.

Twelve pairs of femora were utilised in 72 tests. The experimental investigations were carried out by the author within the departments of Anatomy and Bioengineering at Leiden University, The Netherlands.

3.1 Femoral Preparation

Sixteen matched pairs of human femora with periosteum, were held in a clean condition in frozen storage, harvested from fresh cadavers and placed into storage by the mortuary technician. Of the sixteen pairs of femora, twelve pairs were utilised in the three individual static test sequences within this study.

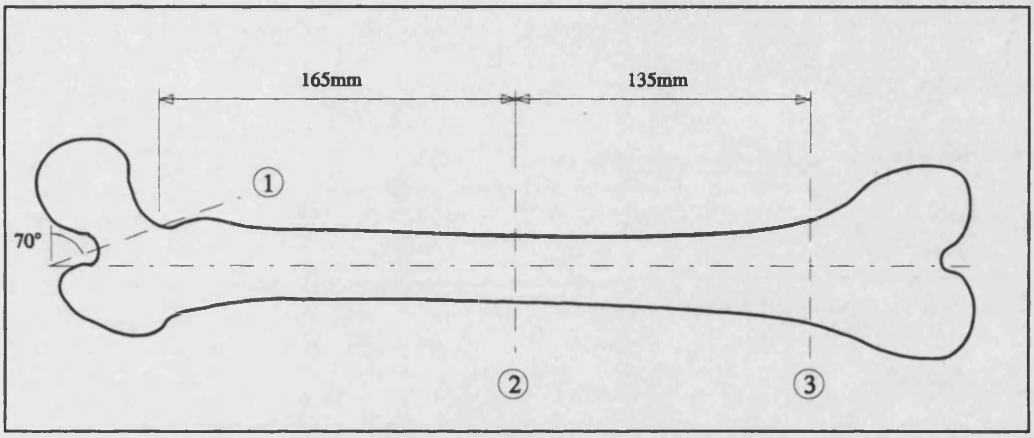

Fig 3.1 - Each femur was divided into the three test sections by cutting the bone at the illustrated positions.

Of the 4 discarded pairs, 3 were isolated due to the small diameter of the mid shaft of the femora and the fourth case because of excessive bowing of the shaft. The ages of the donors at death ranged from 72 to 90, with a mean of 83 years, from two males and ten females.

The bones were removed prior to testing and defrosted at room temperature for six to eight hours. Each femora was clamped in a specially designed cutting template and three saw cuts made using a standard oscillating bone saw (Fig 3.1).

1) The femoral head was removed at 70° to the transverse axis of the femoral shaft, to represent a Pauwels' III type unstable fracture, the high shear forces induced by the almost vertical intertrochanteric fracture line creating instability. The lesser trochanter was also removed to reduce medial support.
2) A cut was made perpendicular to the femoral axis, at a distance of 165mm from the lesser trochanter. This created the proximal and distal sections.
3) The distal condyles were removed perpendicular to the femoral axis, at a distance of 300mm from the fracture line at the lesser trochanter.

The following three tests were performed on each femur:

I a femoral head, lag screw cut-out test, with a simulated unstable intertrochanteric fracture,

II a proximal section failure mode test, with the same simulated unstable intertrochanteric fracture, without medial support, and

III a distal section failure mode test, with a simulated unstable intertrochanteric fracture and a secondary subtrochanteric fracture.

By dividing the femora into the three sections, optimal use of the cadaveric tissue was ensured, while allowing the primary failure modes of the sliding hip screw devices to be isolated. The removal of the femoral head eliminated failure due to lag screw cut-out from the remaining shaft test sequences. The subdivision of the femur allowed the implants to be investigated under different fracture configurations (intertrochanteric and subtrochanteric) experienced clinically, enabling a more in depth analysis of the failure mechanisms and loads.

Within each pair of femora random allocation of the Gamma Nail or DHS was maintained between the left and right side, the same implant design being used for the three individual tests performed on each bone (Appendix A: Table 1). Each test sequence also employed a new implant. The implants were inserted onto the test sections by a consultant orthopaedic surgeon from Leiden Hospital, following surgical techniques outlined by the implant manufactures and employing the correct instrumentation for each implant.

The pairs of femora were prepared for testing as a complete set, consisting of six sections. The six test specimens were X-rayed prior to testing as a group, and again immediately after testing. For each of the three tests on each femur the failure mode was recorded. A simple Student *t* test statistical analysis was completed an all the test results (Appendix C). Any cadaveric sample requires statistical analysis due to the inherently variable nature of tissue and the results of any tests performed on it.

3.2 Femoral Head Tests (I)

3.2.1 Method

For the femoral head lag screw cut-out test a nylon bar was used to represent the femoral neck and shaft, as outlined by Richards *et al* (1990), cut at a corresponding angle to the femoral head, maintaining neck/shaft contact and alignment. Nylon is a stronger material than bone and by using it to replace sections of the femur, it assisted in the isolation of a particular failure mode. The Gamma Nail or DHS plate was implanted onto the nylon section, as if it were the missing shaft. The lag screw was implanted into the femoral head centrally, with an anteversion angle of 10° and the tip of the screw 10mm ± 3mm from the articular surface (Fig 2.9). The insertion technique for the two screws was similar. Both required a guide wire to be inserted into the femoral head, lined up using the supplied jig, to achieve the correct position of the lag screw within the head and a hole for the lag screw was then pre-drilled over the guide wire. Tapping of the hole is optional for the DHS screw but it was not used for this test sequence.

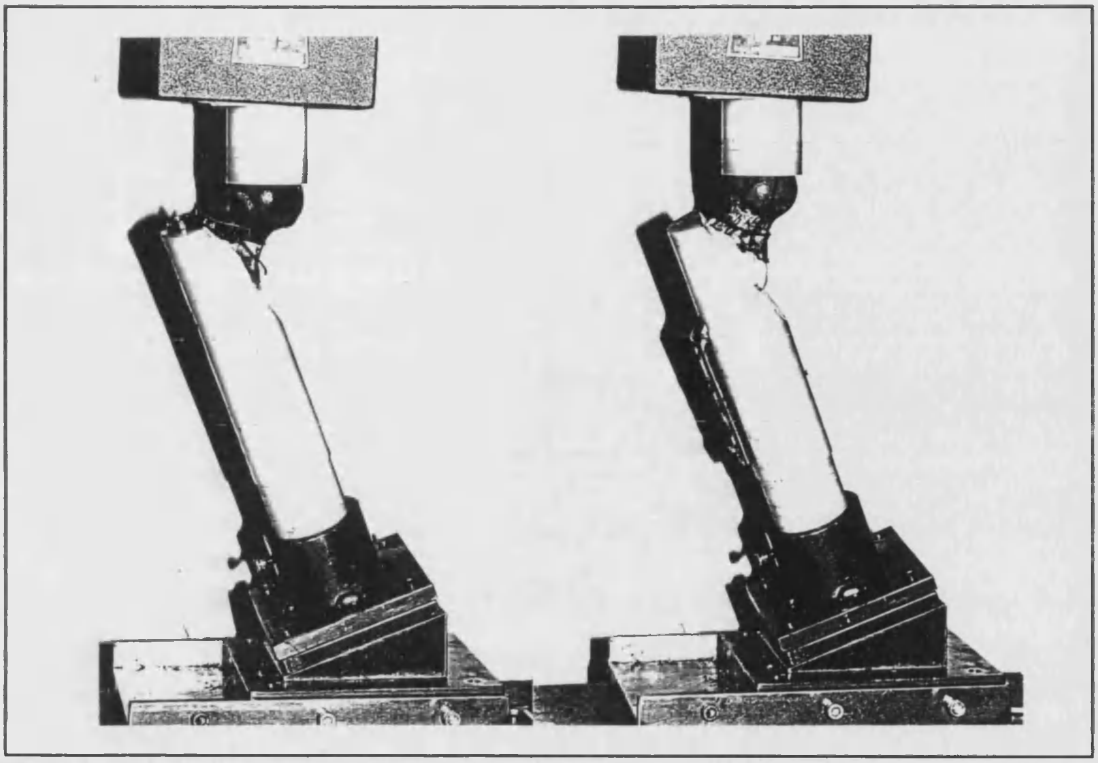

Fig 3.2 - DHS and Gamma Nail femoral head test specimens.

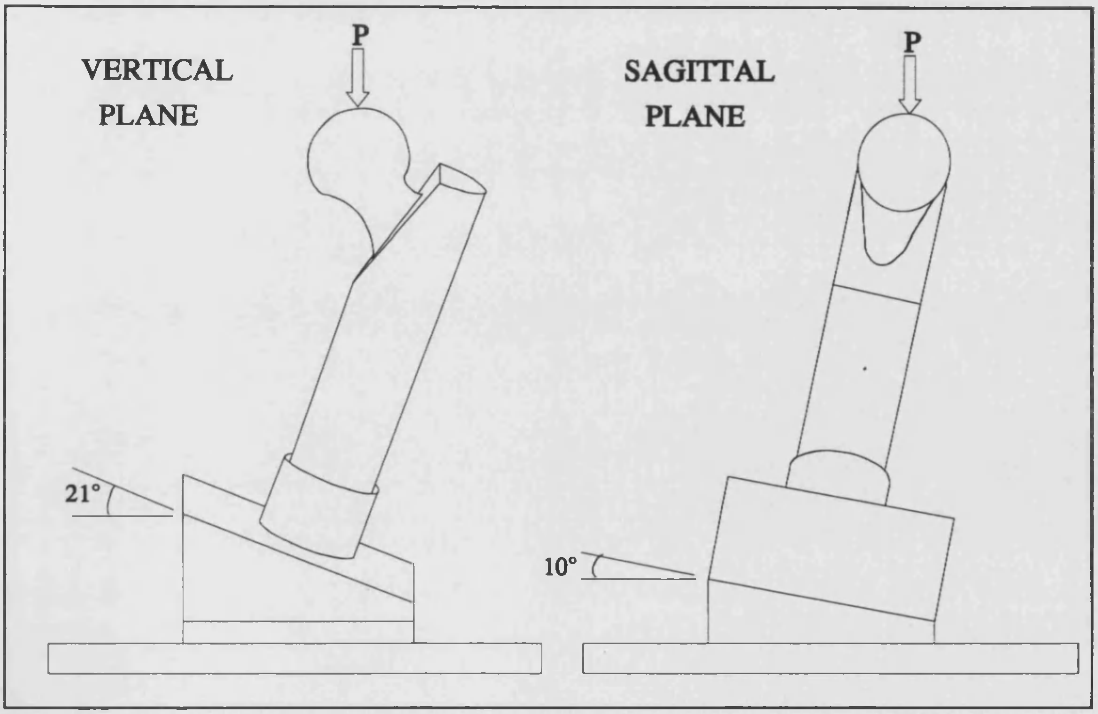

Fig 3.3 - The mounting angles of the prepared implants shown in the sagittal and vertical planes.

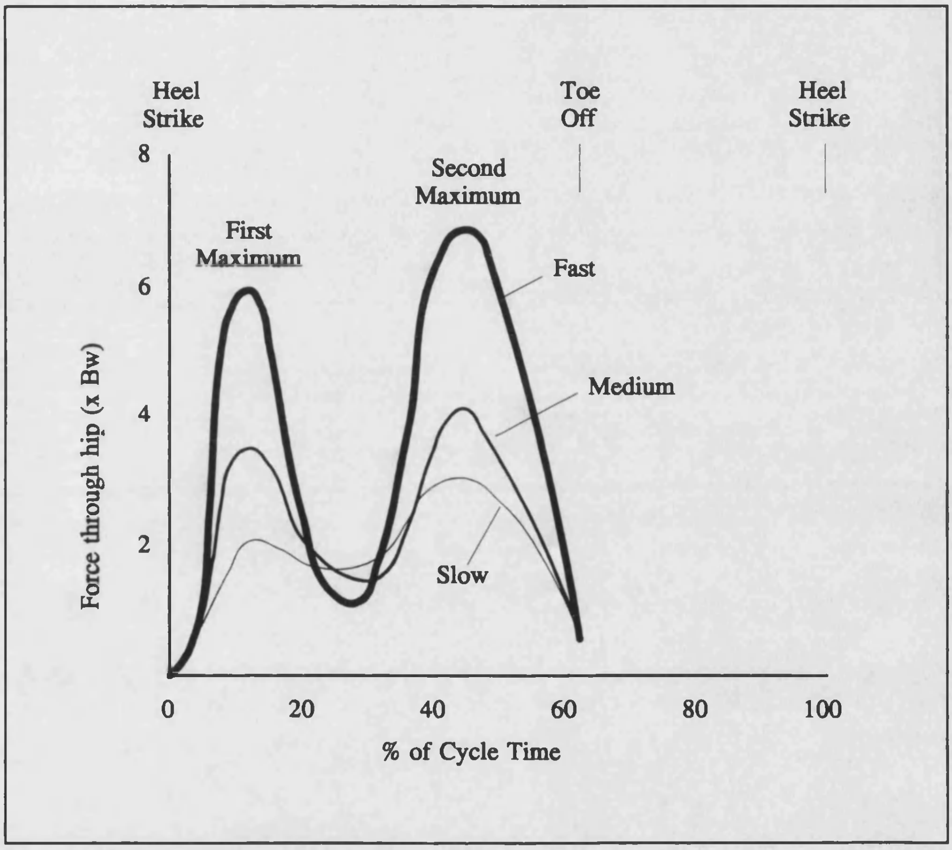

Fig 3.4 - The walking cycle, indicating the positions of maximum hip joint loading (Paul (1971)).

The assembled specimen was mounted in a Hounsfield Testing Machine at 21° in the vertical plane and 10° in the sagittal plane (Figs 3.2 & 3.3). This loading configuration represented the first maximum peak load during a walking phase (Fig 3.4). Paul (1960) calculated the direction of the resultant load at this point to be 21° and 12° (Fig 2.6). The 12° angle was decreased to 10° to accommodate the reduction in the sagittal angle of the femoral axis due to the reduction in femoral length, from raising the mounting point to mid shaft from the distal condyles. The load was applied at the rate of 10mm/min, via a nylon cup, recording the load and displacement until failure.

3.2.2 Results

Failure of the femoral head was identified from a drop in the applied force. The failure modes were identified from post-test X-rays, in cases where the failure mode was not clearly visible. The Gamma Nail lag screw consistently failed due to migration of the screw tip within the femoral head, in all the 12 tests. In comparison the DHS failed in two distinct ways, either screw migration (55%) or screw bending at the implant barrel, where no movement of the screw tip within the femoral head could be identified from the X-rays (Fig 3.5 & 3.6).

The failure load due to bending of the DHS lag screw was around 55% greater than that of screw migration ($p<0.005$) (Appendix C). The mean lag screw lengths protruding from the barrels in these two groups differed by only 0.25mm, so this was not considered to be a major influence on the failure mode. The positions of the screw tips within the femoral heads also appeared to be consistent from pre-test X-rays (Fig 3.7). This lead to the assumption that the quality of the cadaveric bone itself governed the different DHS outcomes. The two failure modes were subsequently divided into two assumed groups, known as 'hard' and 'soft' bone groups, screw migration being associated with the soft bone. The failure load for the Gamma Nail was significantly higher than the DHS in all cases ($p=0.01$) (Fig 3.8) (Appendix A: Table 2). The Gamma Nail failures were correspondingly divided into the two bone groups within each matched pair. The load to failure for the Gamma Nail in the hard bone group was around 90% greater than that of the soft bone ($p<0.02$).

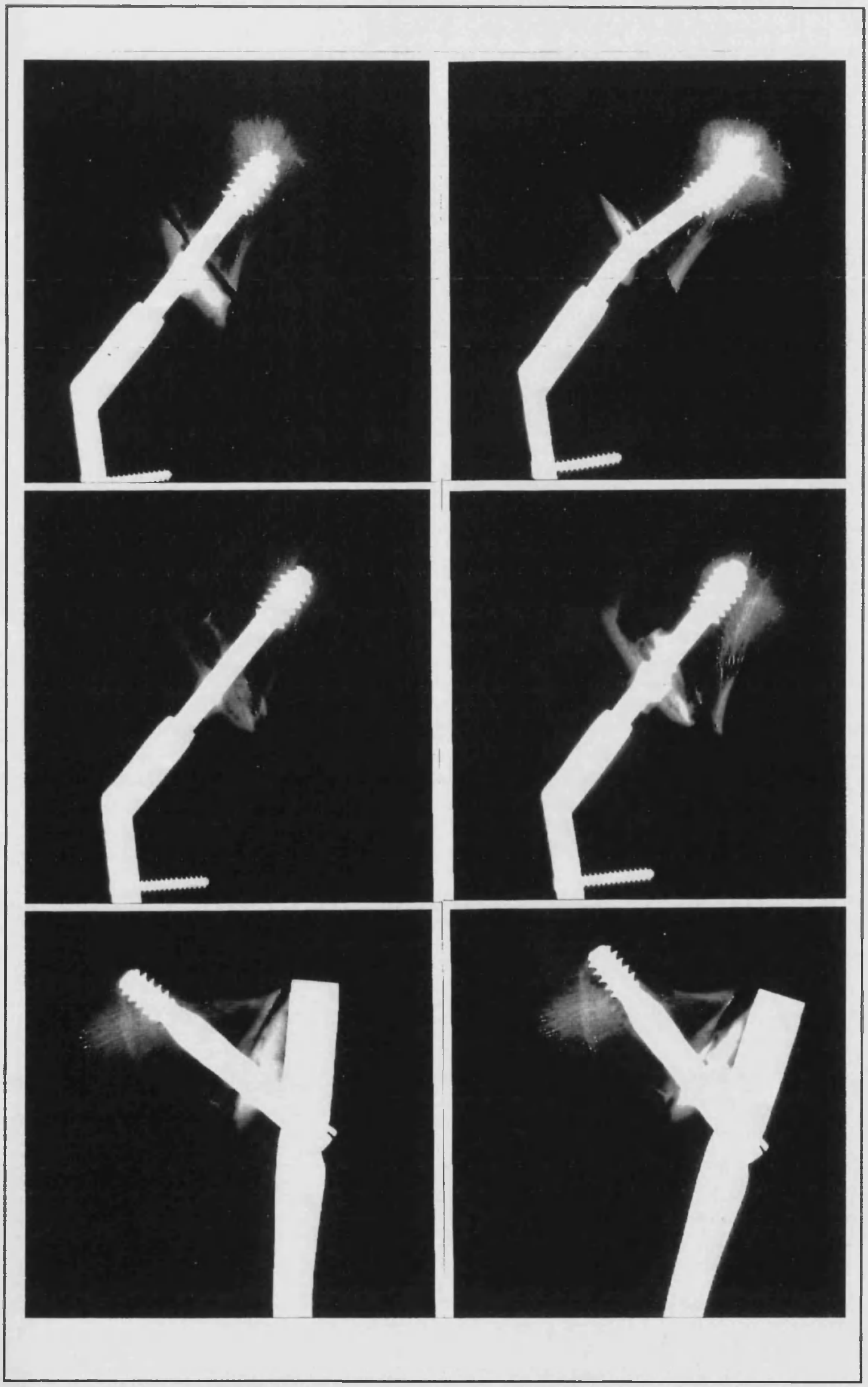

Fig 3.5 - X-Rays showing femoral head failure modes: DHS lag screw bending (top), DHS lag screw cut-out (middle) and Gamma Nail lag screw cut-out (bottom).

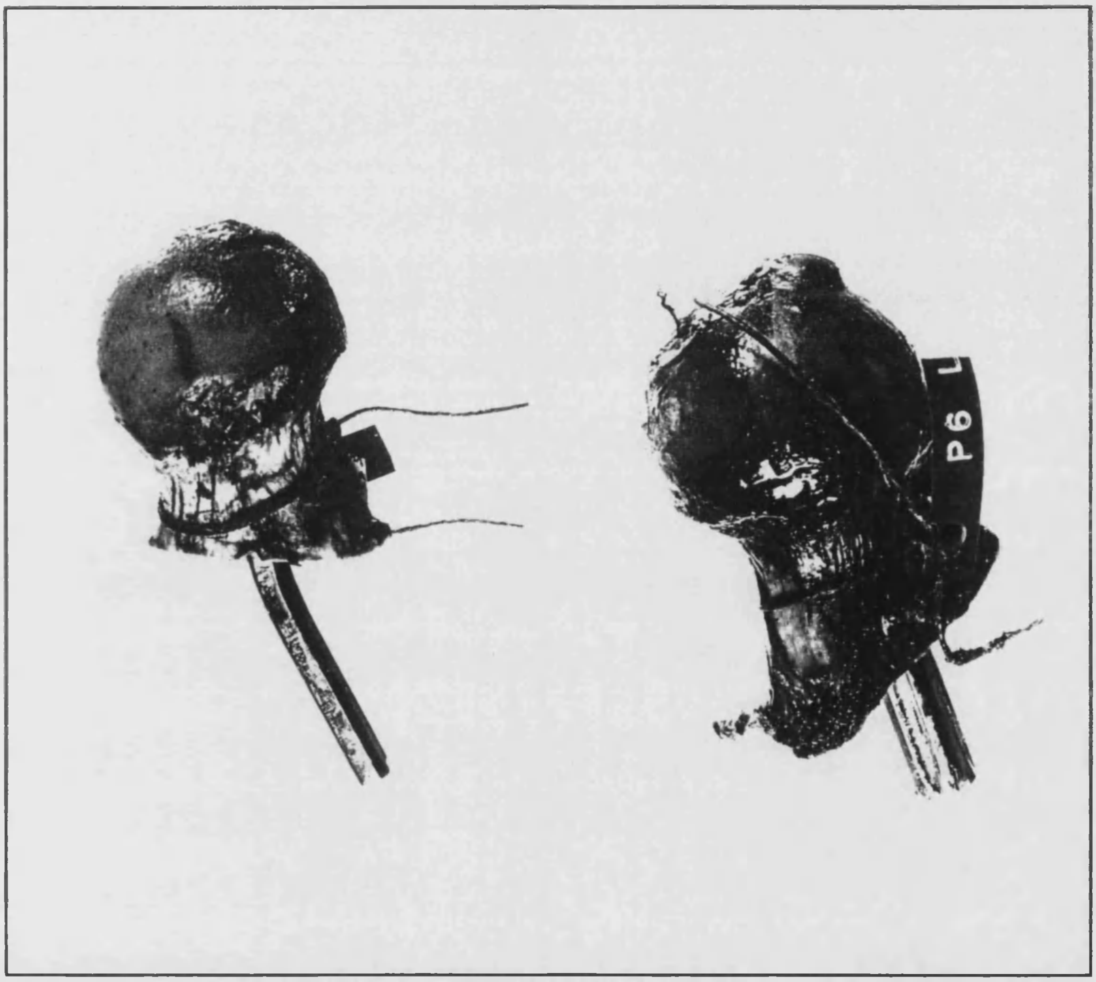

Fig 3.6 - Photographs showing a bent DHS lag screw (left) and a cut-out Gamma lag screw (right).

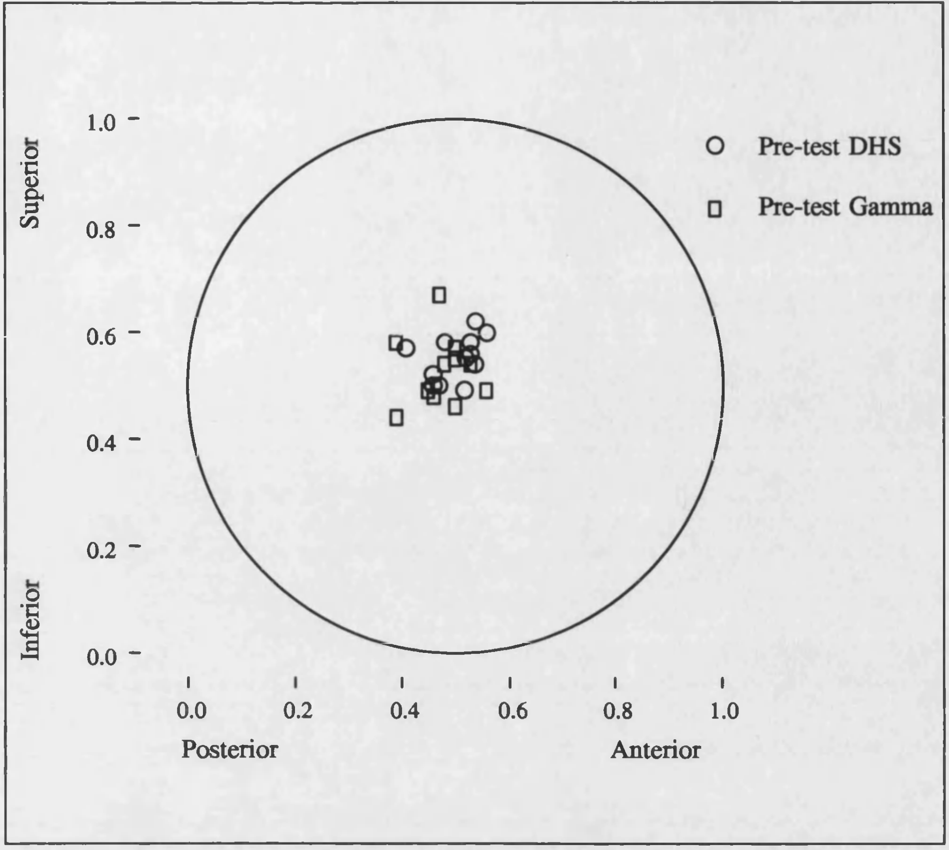

Fig 3.7 - The pre-test positions of the lag screws for the two implants.

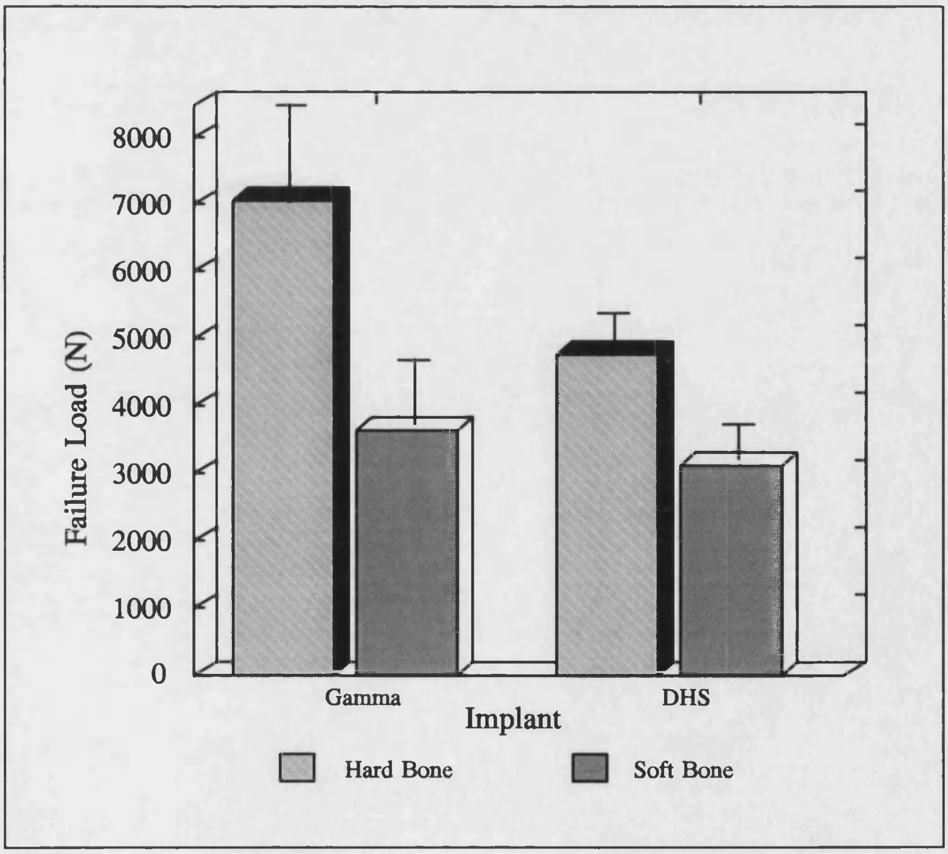

Fig 3.8 - The mean failure loads for the 23 femoral head cut-out tests.

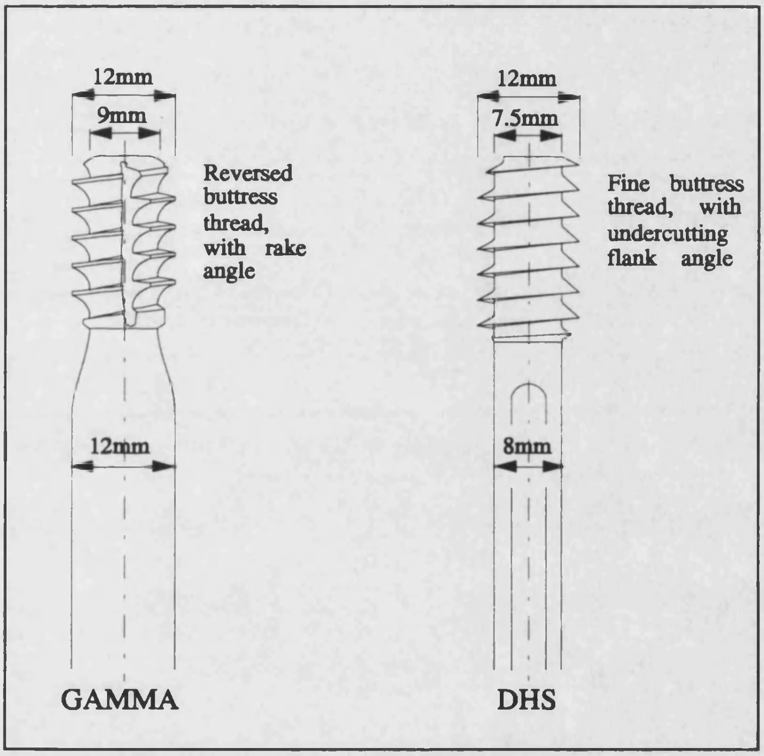

Fig 3.9 - The Gamma Nail and DHS lag screw threads.

Where both lag screws failed due to screw migration, ie. soft bone, the Gamma Nail failed at a mean load around 20% greater than the DHS ($p<0.05$) and for the hard bone group the increase was nearer 50% greater ($p<0.03$).

The Gamma lag screw consists of a reversed buttress thread, with a rake angle cut down either side of the screw to enable self cutting (Fig 3.9). The DHS screw has a standard, fine buttress thread, with an undercutting flank angle. The overall diameters of the two threads are very similar, the only difference being the diameters of the screw shanks, 12mm for the Gamma Nail and 8mm for the DHS. This created a larger load bearing area for the Gamma lag screw and hence a stronger fixation within the femoral head.

The bone classification assumed throughout the analysis of the femoral head tests was continued in the evaluation of the fracture configuration tests.

3.3 Intertrochanteric Tests (II)

3.3.1 Method

The test configuration for the intertrochanteric fracture replaced the removed femoral head and neck with a nylon loading section. The angle of the replacement section duplicated the unstable intertrochanteric fracture line, cut when removing the femoral head. The upper face of the nylon 'head' created a horizontal loading surface when mounted in the test machine, enabling the load to be applied without the need for a femoral 'cup'.

The Gamma Nail or DHS was implanted onto the proximal femoral shaft, without the use of the distal locking screw with the Gamma Nail. The lag screws were inserted into the nylon head with the same 10° anteversion angle as the previous femoral head test. The distal 24mm section of the proximal shaft was then cemented into a metal mounting sleeve using Polymethylmethacrylate (PMMA) bone cement. The same loading conditions of 21° and 10° were again applied (Fig 3.10).

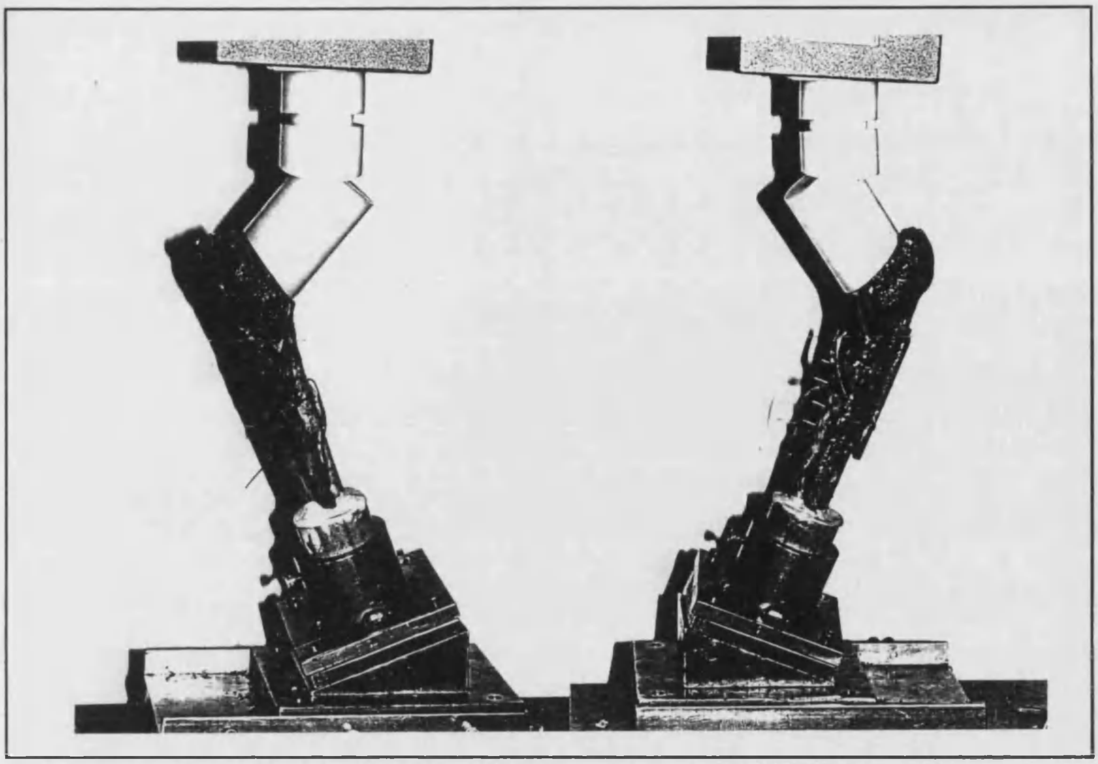

Fig 3.10 - DHS and Gamma Nail intertrochanteric fracture test specimens.

Fig 3.11 - Photograph showing a Gamma Nail shaft fracture.

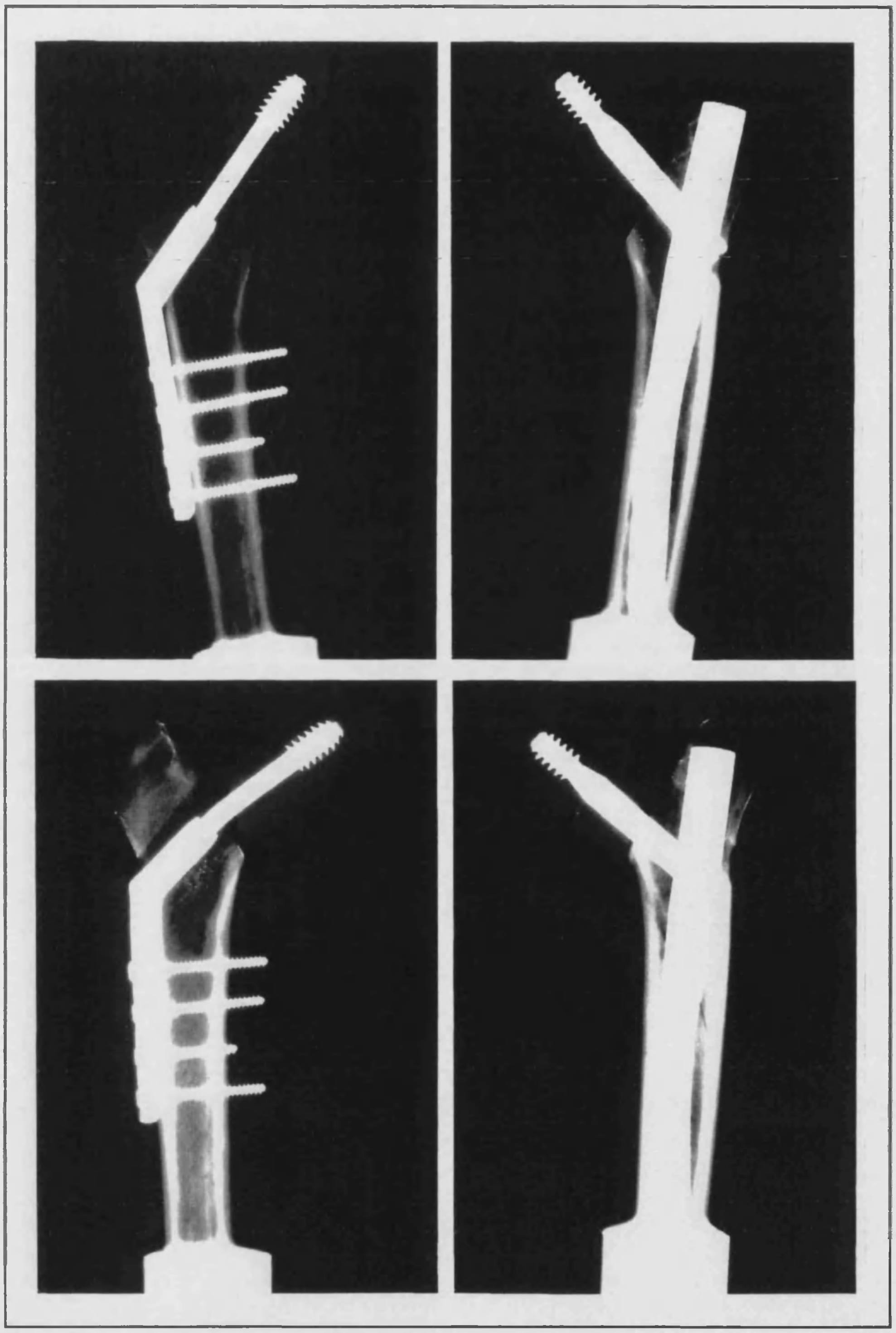

Fig 3.12 - X-Rays showing a DHS failure due to lag screw bending (left) and a spiral fracture around the femoral shaft due to the Gamma Nail 'sinking' (right).

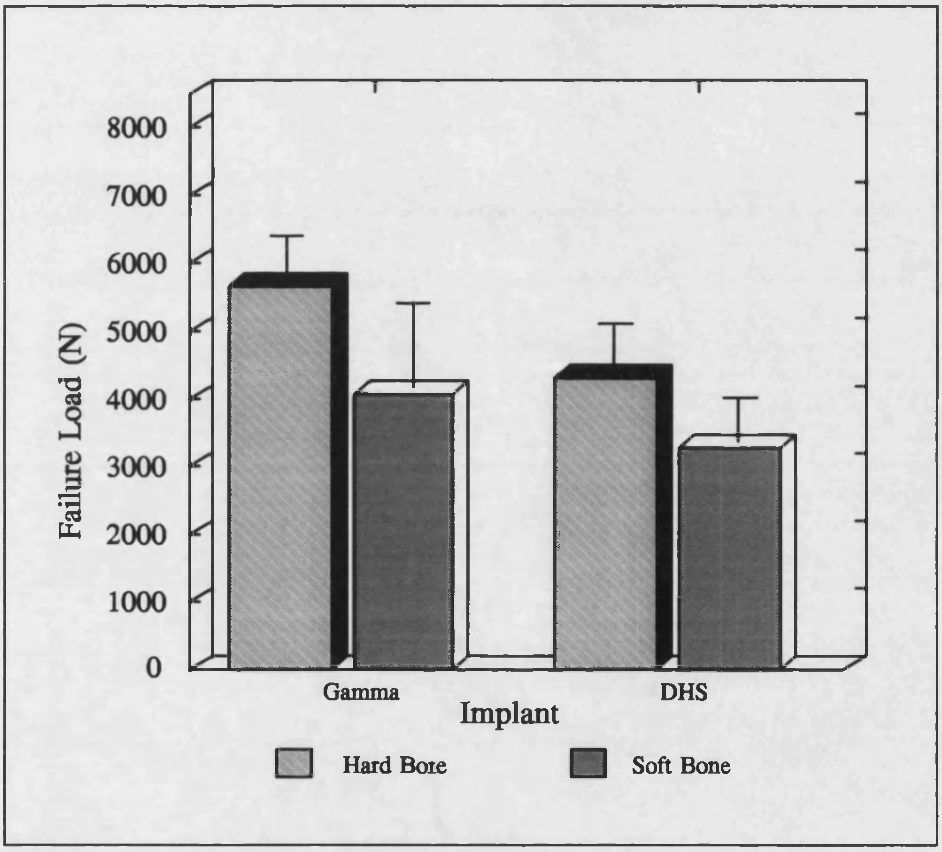

Fig 3.13 - The mean failure loads for the 23 intertrochanteric fracture tests.

3.3.2 Results

The overall mean failure loads for the Gamma Nail, without the distal locking screws, were around 30% greater than those recorded for the DHS. The failure mode identified with the Gamma Nail was as a result of subsidence of the nail within the femoral shaft, in 9 out of the 11 tests completed (Fig 3.11). This caused a mid-shaft fracture around the bend in the nail itself in 6 cases, a vertical fracture below the lag screw entry hole in 4 cases, with the remaining femora fracturing at the top of the metal sleeve in a clean break.

The DHS failure mode was lag screw bending at the barrel in 11 cases (Fig 3.12). This was due to the high shear forces across the fracture site, induced by the unstable fracture. The smaller diameter of the DHS lag screw was not able to withstand these forces, a problem that was not identified with the Gamma lag screw. The remaining failure was a spiral fracture around the bottom cortical screw. It was probable that this was as a result of the drilling of the screw holes where a stress raiser may have been created.

The intertrochanteric test sections were once again classified into the two bone groups within each matched pair. The loads to failure for the Gamma Nail were around 40% greater in the hard bone group than the soft group ($p<0.02$) (Fig 3.13). The hard bone had a greater ability to support the Gamma Nail and prevent it slipping down the shaft, when no distal locking screws were present. This additional support increased the resistance of the hard bone to spiral fractures around the shaft. It was only once this support failed that fractures finally occurred around the bend in the nail.

The DHS also performed better in the hard bone group with a mean load nearly 30% greater ($p<0.05$) than the soft bone, the support provided along the lag screw at the fracture site being superior in the former. The Gamma Nail failed at higher mean loads than the DHS in both bone groups, around 30% with the hard bone, and 25% with the soft bone (Appendix A: Table 3). This suggests that the Gamma Nail would be a stronger implant for use in unstable intertrochanteric fractures of the femur.

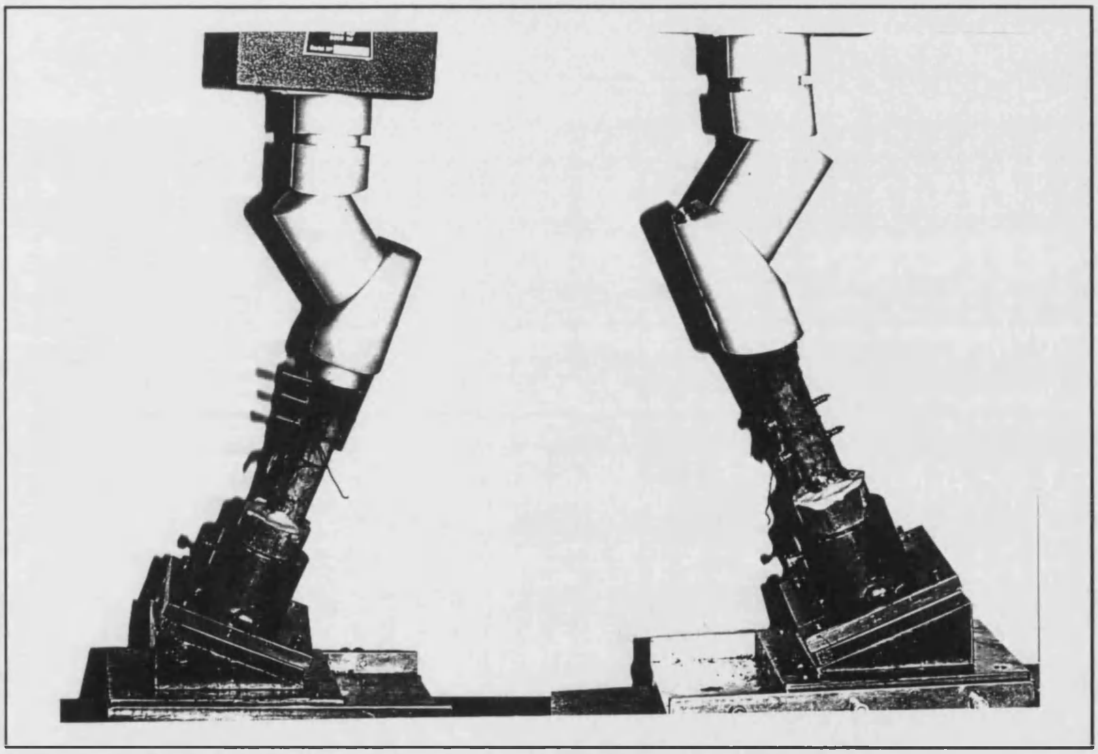

Fig 3.14 - DHS and Gamma Nail subtrochanteric fracture test specimens.

3.4 Subtrochanteric Tests (III)

3.4.1 Method

The test on the subtrochanteric fracture involved the use of two nylon sections, one to replace the removed femoral head and a second for the proximal section and femoral neck of the missing shaft. The experimental preparation and procedure was the same as the intertrochanteric fracture tests but included the use of distal locking screws with the Gamma Nail (Fig 3.14).

3.4.2 Results

The overall mean failure loads for the Gamma Nail, with distal locking screws, were around 50% greater than for the DHS. The Gamma Nails failed around the distal locking screws in 11 of the tests. This was evident by either a spiral fracture appearing around the screws and the tip of the nail or a complete shaft failure (Fig 3.15). The remaining failure was due to a vertical fracture down the length of the femur, possibly caused by the nail pivoting about the distal screws. No subsidence in the position of the nail was identified in any of the tests.

The DHS failed due to cortical screw pull out at the plate in 11 cases which resulted in a spiral fracture around the femora in 7 cases. The other 4 exhibited a vertical fracture down through the line of the screws. The lowest cortical screw was the first to pull out in each case, a result of the highest forces at this point due to the increased perpendicular distance from the bending arm (Fig 3.16). The remaining implant failed due to lag screw bending between the two nylon sections.

With the femora allocated to the respective bone quality groups, the mean failure loads for the Gamma Nail between the hard bone group and the soft bone were comparable (Fig 3.17). This implied that when distal locking screws were used with the Gamma Nail, to prevent the nail subsiding or rotating within the medullary canal, the quality of the bone itself had little effect on the failure loads for the implant. The mean failure loads for the DHS by comparison, were around 45% greater in hard bone than soft bone.

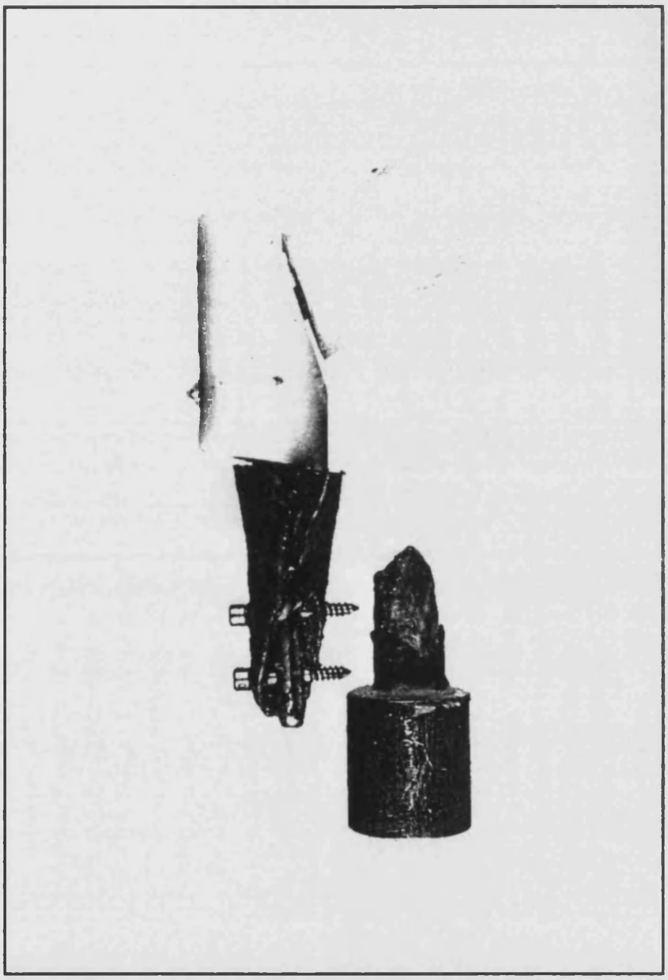

Fig 3.15 - Photograph showing a Gamma Nail shaft fracture at the distal end of the nail.

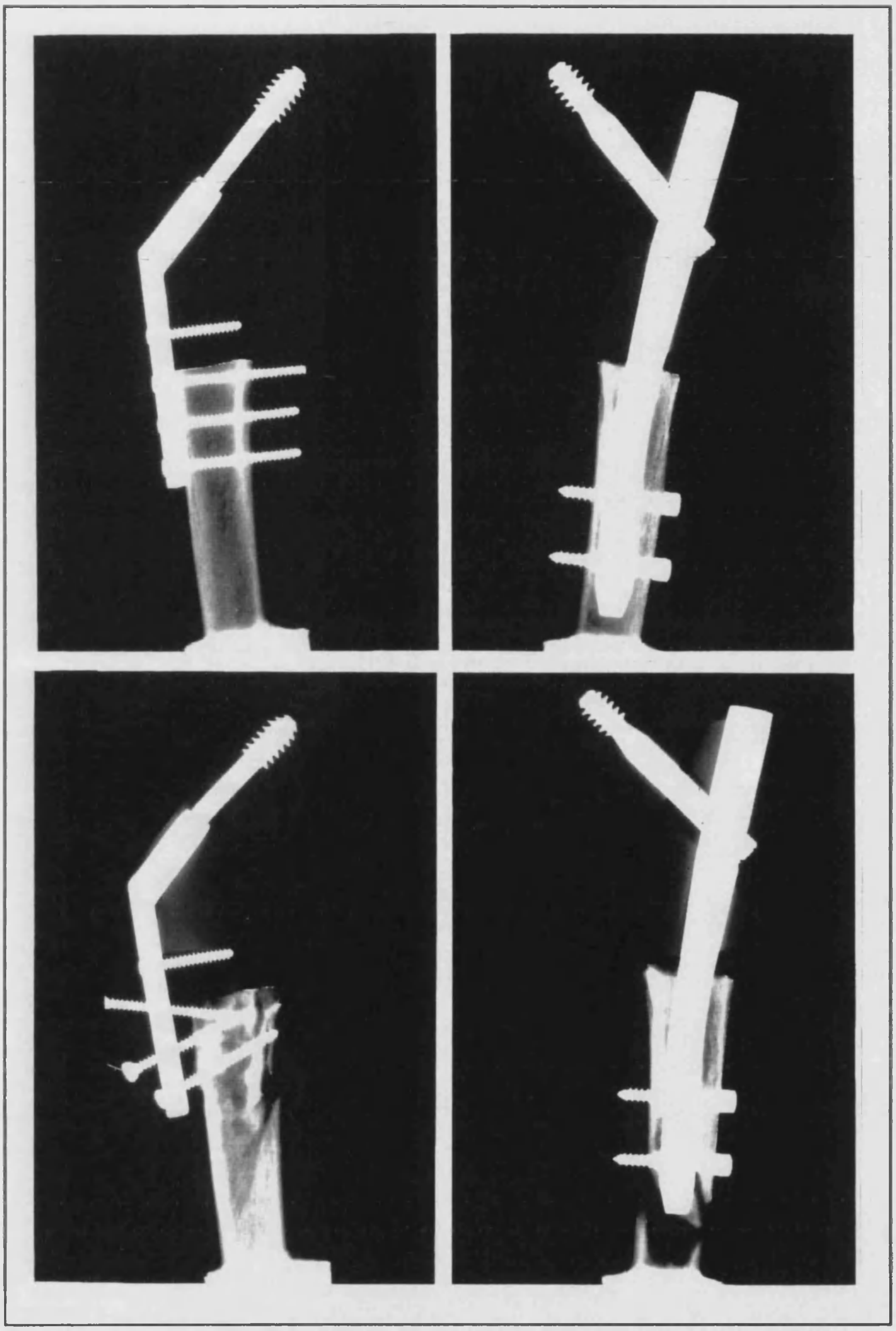

Fig 3.16 - X-Rays showing a DHS failure due to cortical screw pull-out (left) and a Gamma Nail causing a shaft fracture at the base of the nail (right).

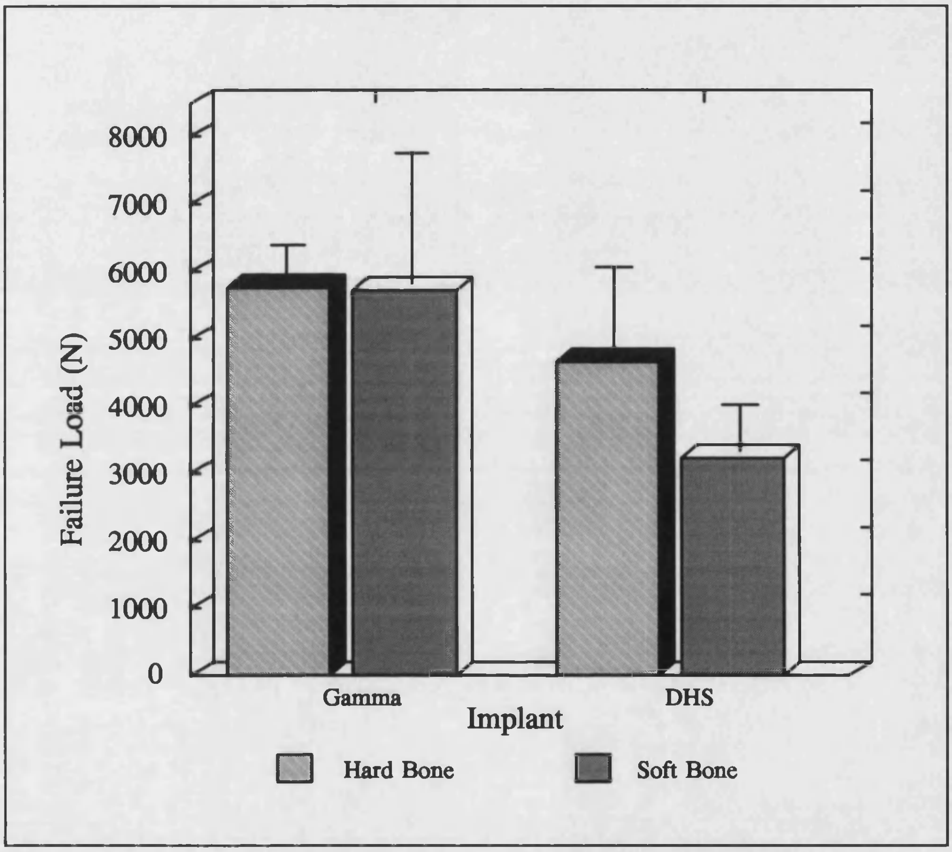

Fig 3.17 - The mean failure loads for the 24 subtrochanteric fracture tests.

This indicated that the hard bone had a greater resistance to the induced forces on the cortical screws. The lateral positioning of the DHS plate compared to the medial positioning of the intramedullary Gamma Nail resulted in increased bending moments on the screws from the greater moment arm. The mean failure loads for the Gamma Nail with hard bone were around 25% higher than for the DHS which was not significant, however in the soft bone group this increase was almost 110% ($p<0.001$) (Appendix A: Table 3).

3.5 Discussion

By undertaking a simple statistical paired test on the failure loads for the three tests (Appendix C), the failure loads for the Gamma Nail appeared to be significantly higher for all three test conditions:

1. $p=0.01$ for the Femoral Head test,
2. $p<0.01$ for the Intertrochanteric Fracture Test and
3. $p<0.01$ for the Subtrochanteric Fracture Test.

Where p = statistical significance

Two individual tests were omitted from the three test sequences. In the femoral head tests, the lag screw was positioned too close to the subchondral bone layer with the DHS lag screw in one case (Appendix A: Table 5) and was therefore excluded from the testing. When preparing this specimen, the bone quality within the femoral head was noted to be of poor quality, resulting in the lag screw penetrating too far into the head. This pair of femora were classified as the 'soft' bone group for the complete set of tests on them. In one intertrochanteric test sequence, the femora were excessively bowed in one pair and the Gamma Nail could not be introduced.

Comparing the behaviour of the Gamma Nail in the two fracture configuration tests (II and III), the highest loads to failure were recorded in the subtrochanteric group, where distal locking screws were used (Fig 3.18). In hard bone the subtrochanteric failure load for the Gamma Nail was only marginally greater than the intertrochanteric failure, whereas with the soft bone, the loads were significantly greater with an increase of around 40% ($p<0.05$). It can therefore be assumed that the distal locking screws enhance the performance of the Gamma Nail when the quality of the bone is poor.

The design of the intramedullary nail itself appeared to result in a consistent overall performance with both fracture conditions. The argument that the Gamma Nail should only be used in cases of subtrochanteric fractures should therefore be questioned. The use of distal locking screws would improve the performance of the nail in all situations regardless of the bone quality, but would be particularly recommended in cases of osteoporotic bone.

The DHS in the hard bone group resisted failure to 10% greater loads with the subtrochanteric fracture than with the intertrochanteric fracture. In the soft bone group the two tests had comparative failure loads. For the DHS in hard bone, both the fracture configuration failure loads performed better than the Gamma Nail in the soft bone without the distal locking screws. Interestingly, in soft bone the DHS performed better with the intertrochanteric fracture as would be expected, but in hard bone the subtrochanteric fracture was better. This subtrochanteric result contradicts clinical performance, which suggests that the short four hole plate used with the DHS would perform better with intertrochanteric than subtrochanteric fractures, due to the increased proximal stability (Goldhagen *et al.* (1993)).

In the subtrochanteric test sequences, the femoral neck of the femur was replaced with a nylon component which gave additional support to the shaft of the lag screw on the lateral side of the fracture line, where bending of the lag screw would occur. The intertrochanteric tests relied on the bone itself to support the lag screw, putting significant importance on the bone quality around the femoral neck region. In the subtrochanteric tests with hard bone, this increased support around the lag screw provided by the nylon, enhanced the overall performance unrealistically, preventing failure due to lag screw bending at a lower load.

The lowest recorded failure loads were for the DHS in the case of the subtrochanteric fracture when the bone was of poor quality.

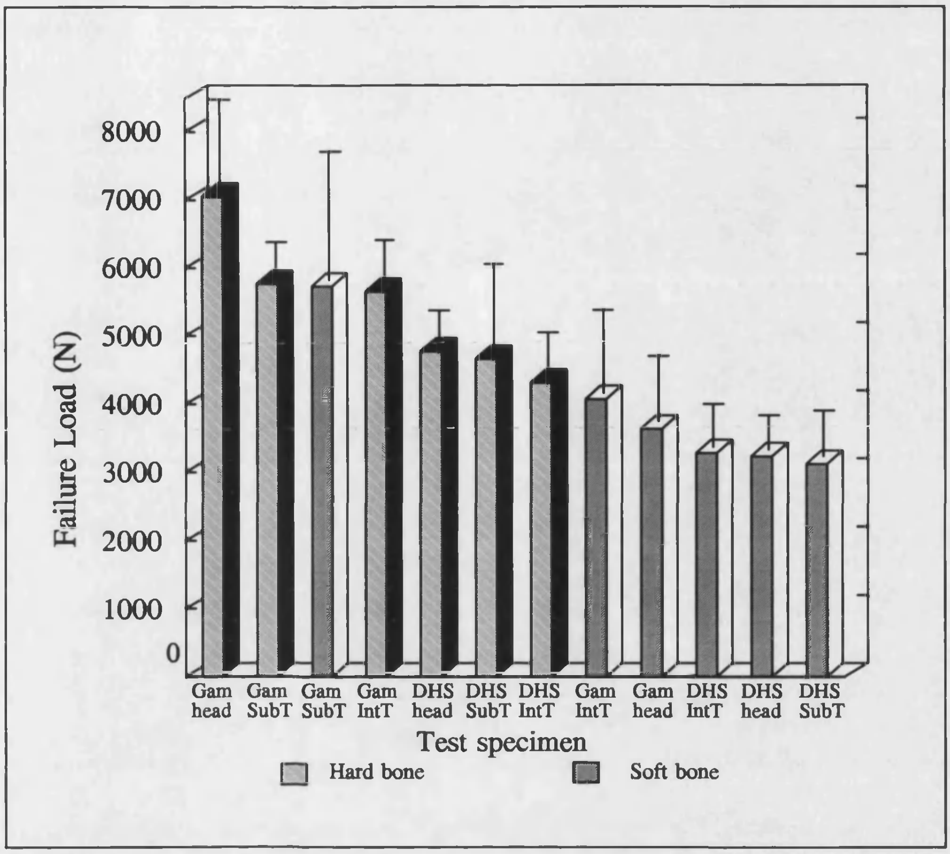

Fig 3.18 - The mean failure loads for the 70 test sequences divided into the bone quality groups.

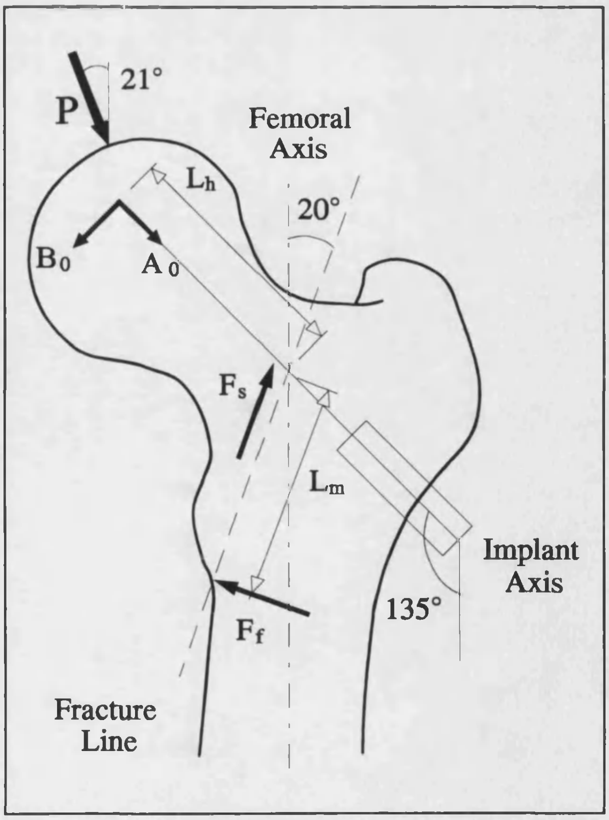

Fig 3.19 - Forces across an unstable intertrochanteric fracture line.

The laterally placed cortical screws in conjunction with the soft bone resulted in the screws pulling out relatively easily. As sliding hip screws are most applicable in elderly patients with poor bone quality such as osteoporotic bone, leading to fractures from falls, the results from the soft bone group were considered to be the closest representation of the clinical situation.

The failure loads for the individual tests can be expressed more clearly in terms of the multiples of body weight at which the failures would occur.

The multiples were calculated by assuming the body weight (B'weight) of a typical person to be 70kg, with the resultant load acting at 21° (Kyle *et al.* (1980)).

GAMMA	x B'weight	DHS	x B'weight
Head migration/soft bone	5.29	Head migration/soft bone	4.54
Head migration/hard bone	10.26	Screw bending/hard bone	6.95
Intertrochanteric/soft bone	5.92	Intertrochanteric/hard bone	4.77
Intertrochanteric/hard bone	8.23	Intertrochanteric/soft bone	6.27
Subtrochanteric/soft bone	8.34	Subtrochanteric/soft bone	4.70
Subtrochanteric/hard bone	8.39	Subtrochanteric/hard bone	6.79

By dividing each femora into the three test sections, the individual failure modes were isolated from one another. The most common clinical failure of lag screw cut-out from the femoral head was explored in the femoral head tests and in the majority of individual cases the Gamma Nail failed at greater loads than the DHS under equivalent conditions. From the failure loads shown above, the femoral head cut-out/migration loads for the DHS are equivalent to loads at a medium pace (4.1 x B'weight). The loads through the joint as a result of a stumble were recorded by Bergmann *et al.* (1990) to be 8 x B'weight, under which conditions the majority of the failure modes could occur.

Considering the femoral head failure loads, in comparison with the failure loads for the intertrochanteric and subtrochanteric fractures, it was evident that when bone quality was poor the failure mode for both implants would be due to cut-out/migration of the lag screw. This required the lowest failure load for the Gamma Nail and would have done so for the DHS without the additional support of the nylon in the subtrochanteric tests. The next most common cause of failure for the DHS would be failure of the implant itself due to lag screw bending.

Doherty *et al.* (1978) estimated that the average cross-sectional area of a femoral head was 1809mm^2 at the superior position and 907mm^2 at the neck. Comparing the percentage of the femoral head and neck taken up by the DHS lag screw (2.8% and 5.5%) and the Gamma Nail lag screw (6.3% and 12.5%) it is evident that the latter removes a significantly greater proportion of cancellous bone, which could have adverse consequences particularly in small femoral necks. However, in this study the increased diameter of the lag screw resulted in a greater resistance to cut-out, shown by the poor bone quality results, despite the greater volume of bone displaced by the load bearing shaft. The larger lag screw diameter also provided sufficient strength to resist bending of the lag screw under all conditions.

In a simple bending test on an isolated 135° DHS and Gamma Nail, both with a lag screw length of 70mm, the bending moments at the point of exit of the barrel which resulted in bending of the lag screw (DHS) or deformation of the barrel itself (Gamma Nail) were 104Nm and 262Nm respectively (Appendix D). From a simple resolution of forces across the fracture site, the bending moment at the lag screw/barrel junction for the femoral head tests and the intertrochanteric tests could be estimated (Fig 3.19).

P = Applied force @ 21°

ß = Implant angle = 135°

F_s = Shear force at fracture line

F_s = Shear force at fracture line

L_n = Lag screw length

L_h= Lag screw length beyond fracture

L_m= Distance from lag screw to medial cortex

A_0= Axial implant force = Pcos(159°-ß)/4

B_0= Perpendicular implant force = Psin(159°-ß)/4

The following assumptions were made for the simplification:

1. 25% of the applied load is supported by the implant, the remaining 75% by the bone itself. (Frankel (1960))

2. The load at the fracture site is carried perpendicular to the fracture line at its medial end. (Gill *et al.* 1989)

3. The axial implant force does not act across the fracture line. (Gill *et al.* 1989)

At fracture line / lag screw junction

Resolving vertically	$0.75P\cos21° + B_0\cos45° = F_s\cos20° + F_f\cos70°$
Resolving horizontally	$0.75P\sin21° + B_0\sin45° = -F_s\sin20° + F_f\sin70°$
Gives	$F_f = 0.45P$
and	$F_s = 0.66P$

A further assumption must be made that the forces causing lag screw bending are the resultant forces acting on the fracture line, F_s and F_f.
Therefore

$$\text{Bending moment at barrel} = F_s\cos25°(L_n-L_h) + F_f\sin25°L_m$$
$$= 0.66P\cos25°(L_n-L_h) + 0.45P\sin25°L_m$$

From the X-rays of the DHS femoral head test specimens that failed due to lag screw bending, the mean values for the lag screw measurements were established (L_n = 70mm, L_h = 44mm and L_m = 26mm) (Appendix A: Table 6). From these, the value for the bending moment at the point of failure was calculated as 100.2Nm. The DHS lag screw bent at 104Nm in isolation which implied that the assumptions in this calculation were valid. Where the lag screw failed due to screw cut-out in the soft bone group, the bending moment at failure was only 65Nm.

If the same distances were assumed for the Gamma Nail in situ, the resulting calculated bending moment was 147Nm in the hard bone and 76Nm in the soft bone. The Gamma Nail lag screw did not bend in the isolated implant test, but the barrel became severely deformed at the point of exit of the lag screw at 262Nm. None of the loads attained throughout the cadaveric Gamma Nail testing would therefore have resulted in lag screw bending or barrel deformation.

3.6 Closure

The cadaveric study results have consistently supported the clinical literature, indicating that the most common failure mode would be lag screw cut-out. The simple force analysis suggested that in cases where the bone quality was good, ie. able to support 75% of the resultant load through the joint, the DHS implant would fail due to bending of the lag screw, a failure not identified with the larger Gamma Nail lag screw.

All the failures identified in the literature were observed in the cadaveric tests except breakage of the implant itself. This is a fatigue failure mode and as such would require a cyclic loading configuration to recreate it. The failure loads were all significantly lower in the soft bone group than in the hard bone group. The clear differentiation between the two groups for the three test sequences supported the assumption that the femora could be subdivided by bone quality. As osteoporotic bone would be of a poor quality, the results in the soft bone groups were considered to be the closest representation of the clinical failures. In the soft bone group, DHS failures of lag screw cut-out with intertrochanteric fractures and lateral plate pull off for subtrochanteric fractures, were observed. The Gamma Nail also failed due to lag screw cut-out or shaft fracture for the intertrochanteric tests and shaft fractures with the subtrochanteric tests. The Gamma Nail lag screw appeared to resist cut-out failure better than the DHS due to its larger shaft diameter. The overall performance of the intramedullary nail was significantly improved when distal locking screws were used to prevent subsidence of the nail down the femoral shaft.

The more complex shaft failures could not be analysed by simple force resolution as the load transfer mechanisms between the implants and the bone down the femoral shaft were not know. Further analysis of this loading regime must therefore be undertaken.

Chapter 4

STRAIN ANALYSIS STATIC STUDY

The cadaveric study undertaken in chapter 3, highlighted the range of failure modes associated with both the DHS and the Gamma Nail. All the failure modes recorded have also been identified in clinical literature (section 2.5) with a range of associated failure rates. A strain gauge study has also been undertaken to establish the loading patterns in a proximal femur implanted with a Gamma Nail or a DHS, the objective being to provide analysis of the load transfer mechanisms between the implants and the bone. By taking the strain readings on a complete femur, an unfractured implanted femur and a fractured implanted femur, the change in strain between the different fracture situations would provide a comparative picture of the loading regimes for different bone healing conditions.

Previous strain gauge studies have looked at the loading down the femur for the individual implants, with no direct comparison between the DHS and the Gamma Nail. A study by Rosenblum *et al.* (1992) recorded strain reading from cadaveric femora with the Gamma Nail implanted and compared the results to a previous DHS study on unmatched cadaveric bone. It was intended to removed the variability introduced by cadaveric tissue by utilising composite femoral bone models.

4.1 Composite Femoral Bone Models

Sawbone composite femora are manufactured by Pacific Research Laboratories Inc., (Vashon Island, WA. USA) for use in mechanical comparative testing of orthopaedic implants. They consist of a glass fibre reinforced epoxy around a polyurethane foam, to represent the cortical and cancellous bone layers respectively. They are commercially available in either adult or adolescent femur dimensions. Their use removes the variability in dimensions and properties introduced by cadaveric specimens and the availability and handling problems involved with tissue (Fig 4.1).

Several studies have been undertaken to compare composite and cadaveric femora (Beals (1987) & Bianco *et al.* (1989)) with favourable results. Szivek *et al.* (1993 & 1990) compared the material properties and the overall mechanical properties of the composite bones. They concluded that torsional stability was consistent between cadaveric bone and composite, but that the axial stiffness was lower. Their testing of the reinforced epoxy and the foam in isolation found the material properties very similar to the published results of bone properties.

In a different study (Szivek *et al.* (1991)), the same authors found the sawbones to be more flexible than cadaveric bone, so they suggested that any strain measurements taken on implanted composites should be reported as a percentage of the pre-implantation strains. They also stated that cadaveric strains cannot be accurately determined from the composite results, but the way in which implants would change the strain patterns could be assessed. Christofolini *et al.* (1996) undertook a comprehensive study looking at the performance of the composite femur in comparison to human fresh frozen and dried-rehydrated bone. Axial deflexion and strain distribution along with bending and torsional stiffnesses were compared with the a similar conclusion, that the model was suitable for comparative analysis, with good reproducibility.

4.2 Femoral Preparation

Three adult Sawbone femora were utilised in the strain analysis study. On each one an initial cut was made perpendicular to the femoral axis, at the distance of 200mm from the lesser trochanter, removing the distal section of the femur to create a single proximal test section. The intertrochanteric fracture line was drawn at 70° to the transverse axis of the femoral shaft, to represent a Pauwels' III type unstable fracture once again. The distal 24mm section of the proximal femoral shaft was then cemented into a metal mounting sleeve using PMMA bone cement. Six single uniaxial 350 ohm strain gauges (Micro-Measurements) were situated down the proximal femora (Rosenblum *et al.* (1992)), aligned vertically along the direction of principal strain (Chang *et al.* (1987)), on both the medial and lateral cortices.

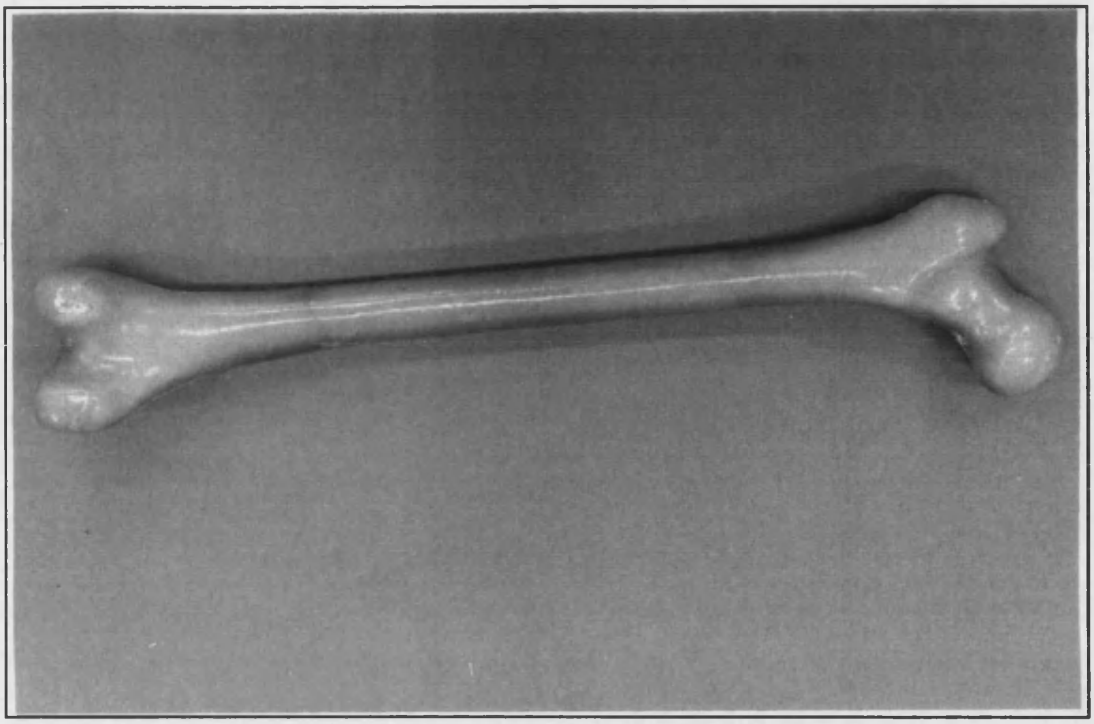

Fig 4.1 - A photograph showing a complete Sawbone composite femora.

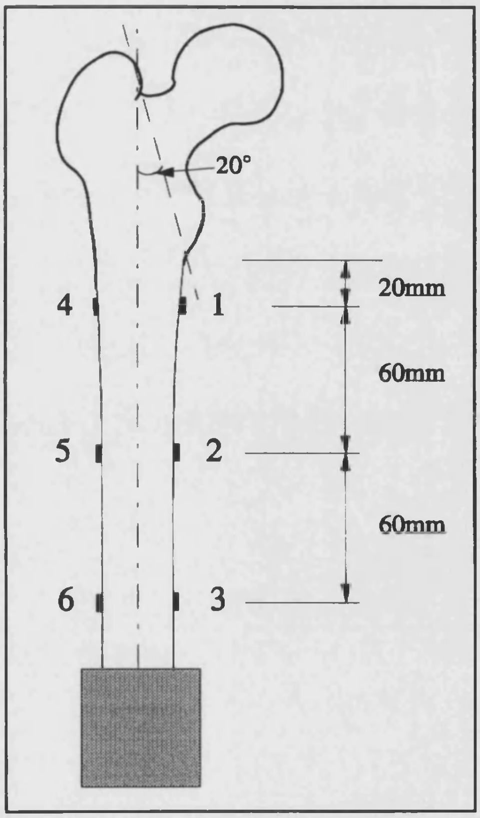

Fig 4.2 - The position of the six strain gauges down the proximal femur

The Gauges were placed in the following positions (Fig 4.2):

Gauge 1	20mm below the lesser trochanter on the medial cortex (P),
Gauge 2	80mm below the lesser trochanter on the medial cortex (M),
Gauge 3	140mm below the lesser trochanter on the medial cortex (D),
Gauge 4	directly opposite gauge 1 on the lateral cortex (P),
Gauge 5	directly opposite gauge 2 on the lateral cortex (M),
Gauge 6	directly opposite gauge 3 on the lateral cortex (D).

4.3 Strain Analysis Study

4.3.1 Method

Three Sawbone femora were utilised in a series of strain analysis tests to compare a DHS, a Ø12mm and a Ø14mm Gamma Nail, the different implants used in the cadaveric study. Each implant was tested under fully healed conditions, where the fracture line was not cut, and at post-operative fracture conditions with an anatomically reduced fracture. For each test, the femur was mounted in an Instron Testing Machine at 21° in the vertical plane and 10° in the sagittal plane, using the same mounting jig as the cadaveric study (Fig 4.3). The load was applied at the rate of 10mm/min, via a nylon cup, recording the load and displacement continuously from 0N to 1800N. Strain measurements were taken at the six gauge positions using an ADU (Autonomous Data acquisition Unit) linked into the Mowlem ADU Dialog software package. Three individual tests were completed for each test configuration. The strain reading were all calculated as the percentage of the strain in the intact femur

The implants were inserted onto each Sawbone using the same surgical techniques as the cadaveric study, by a senior orthopaedic registrar at the Royal United Hospital, Bath. The Ø12mm and Ø14mm Gamma Nails were reamed distally to Ø14mm and Ø16mm respectively as outlined by the implant manufacturers. The lag screws were inserted into the nylon head with the same anteversion angle as used in the cadaveric tests. Once again, the insertion technique for the two screws was similar, with no tapping of the hole for the DHS lag screw.

Each femur was implanted with the following implants for the test sequence carried out on it:

Femur I	135° DHS,
Femur II	135° Ø12mm Gamma Nail,
Femur III	135° Ø14mm Gamma Nail.

The following test sequences were then completed on each femur.

Femur I	1)	The unfractured femora.
	2)	The fully healed fracture configuration implanted with a DHS.
	3)	The post-operative fracture configuration implanted with a DHS.
Femur II	1)	The unfractured femora.
	2i)	The fully healed fracture configuration with the 12mm Gamma Nail without distal locking screws (hole drilled).
	2ii)	The fully healed fracture configuration with the 12mm Gamma Nail with one distal locking screw.
	3i)	The post-operative fracture configuration with the 12mm Gamma Nail without distal locking screws (hole drilled).
	3ii)	The post-operative fracture configuration with the 12mm Gamma Nail with one distal locking screw.
Femur III	1)	The unfractured femora.
	2i)	The fully healed fracture configuration with the 14mm Gamma Nail without distal locking screws (hole drilled).
	2ii)	The fully healed fracture configuration with the 14mm Gamma Nail with one distal locking screw.
	3i)	The post-operative fracture configuration with the 14mm Gamma Nail, without distal locking screws (hole drilled).
	3ii)	The post-operative fracture configuration with the 14mm Gamma Nail, with one distal locking screw.

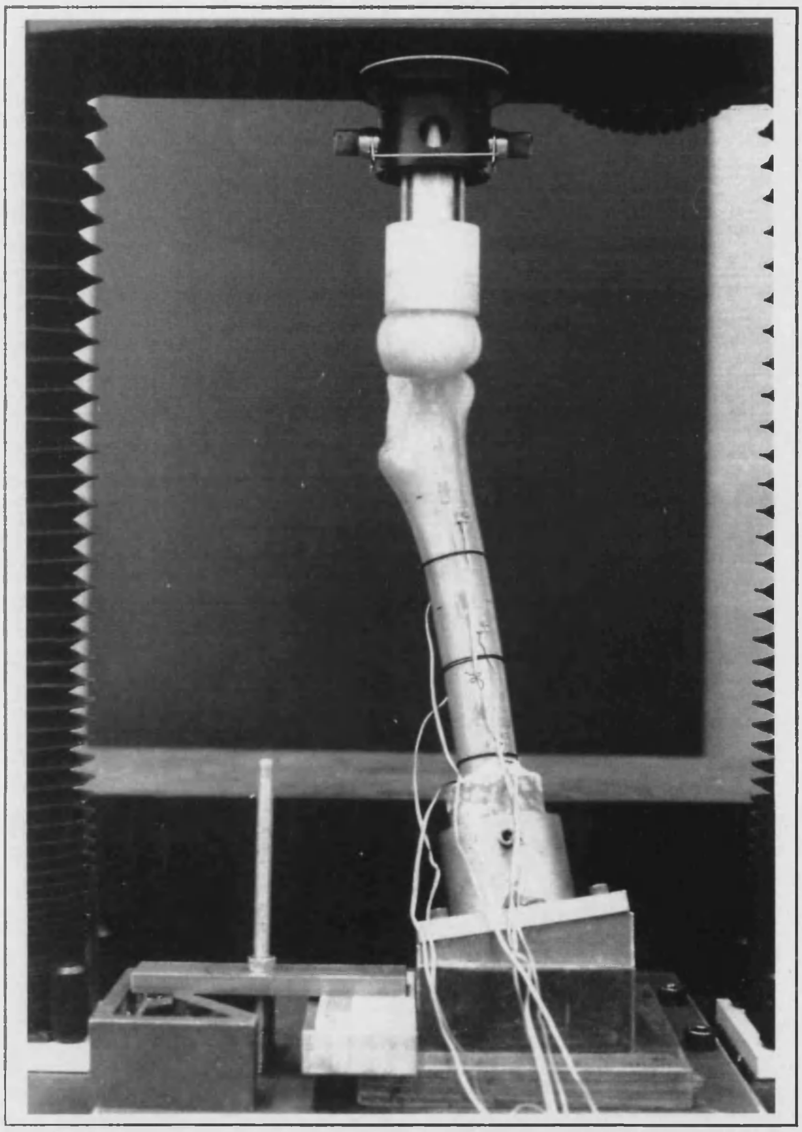

Fig 4.3 - A photograph showing a strain gauged Sawbone in the Instron test machine.

4.3.2 Results

Femur I

In the intact femur the strain behaved linearly at the six gauge positions (Fig 4.4). Maximum loading of the femur was apparent at the proximal gauges (1 and 4), with a reduction distally. A higher compressive strain was recorded at the proximal medial gauges (1 and 2) than at the lateral gauges (4 and 5). At gauge 6, the strain was compressive on the lateral cortex. A simple explanation for this anomaly was that the line of loading passed between gauge positions 5 and 6 and above gauge 1, due to the 21° angle in the vertical plane.

After insertion of the DHS on the unfractured femur, there was no change in the compressive strain at the proximal medial gauge (1) and a decrease in the compressive strain at the two distal medial gauges (Appendix A: Table 7) of 137 μstrain at gauge 2 (82%) and 106 μstrain at gauge 3 (1.2%), approximately 10% of the strain at gauge 1 (Fig 4.5). As expected, on the lateral surface there was a decrease in the tensile strain by 177 μstrain at gauge 5 (54%) and a relative increase in the compressive strain by 113 μstrain at gauge 6 (131%). Gauge 4 was removed when the DHS was inserted as it was positioned at the lateral point of insertion of the lag screw. The insertion of the implant, representing the DHS with a fully healed fracture, did not alter the overall strain pattern experienced by the proximal femur. The reduction in the medial compressive strain and lateral tensile strain suggested that the implant was simply supporting a percentage of the applied load and thus reducing the strain experienced by the femur.

In the test sequence on the fractured femur, the compressive strain was significantly reduced by over 500 μstrain at gauge 1 (57%) and almost 400 μstrain at gauge 2 (50%). No readings were taken at gauge position 4, and with gauge 5 the strain had become almost zero (3%). The reduced stability of the femoral head and neck with the DHS lag screw, caused an increase in the angle of load application with respect to the femoral axis. The line of load bearing then passed closer to gauge position 5 and caused a reduction in the strain at this point. Under this unstable fracture condition, the load appeared to be transferred down to the distal section of the femur, gauge 6 increasing in compressive strain by around 600 μstrain (298%).

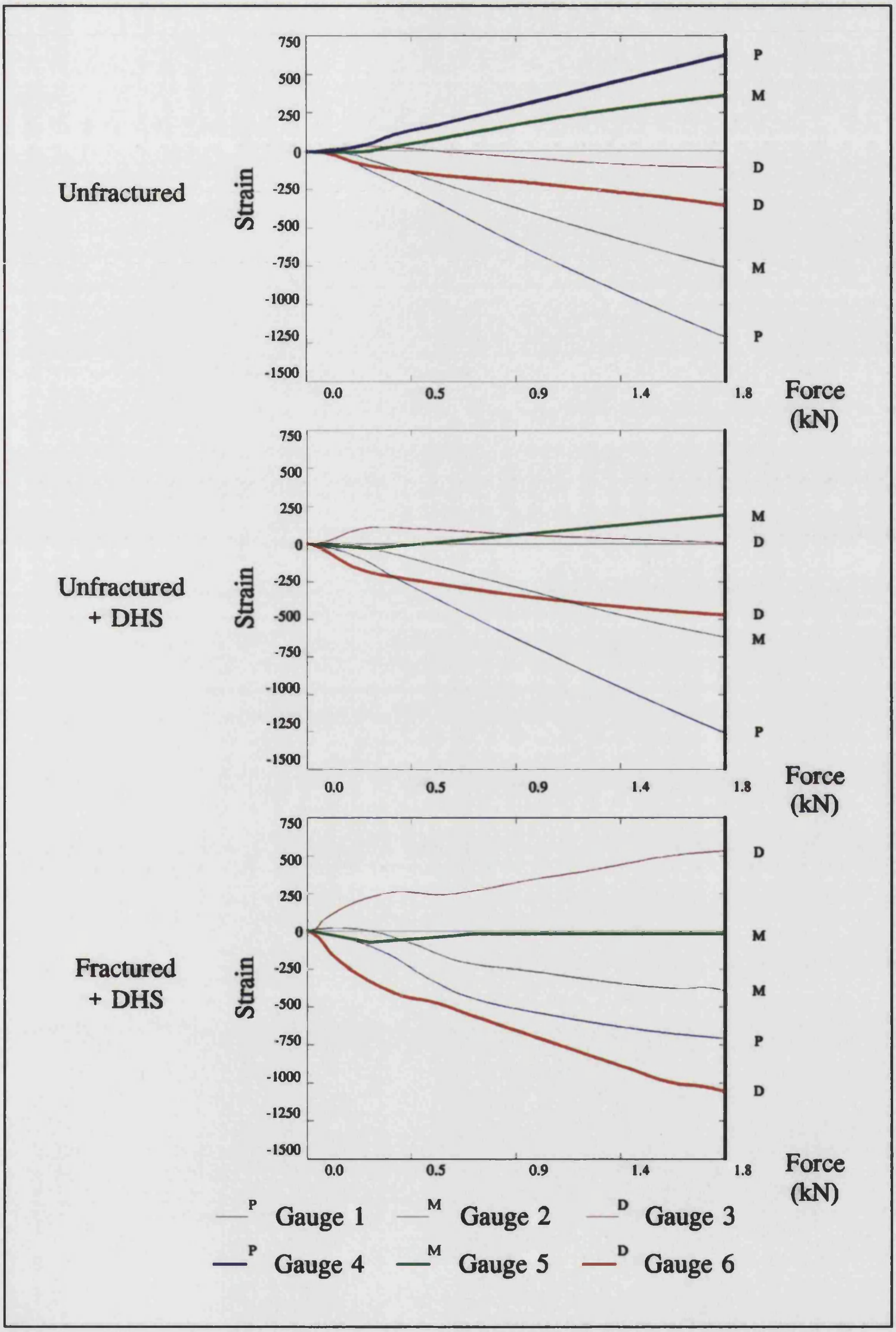

Fig 4.4 - The strain versus load characteristics at the six gauge positions on Femur I.

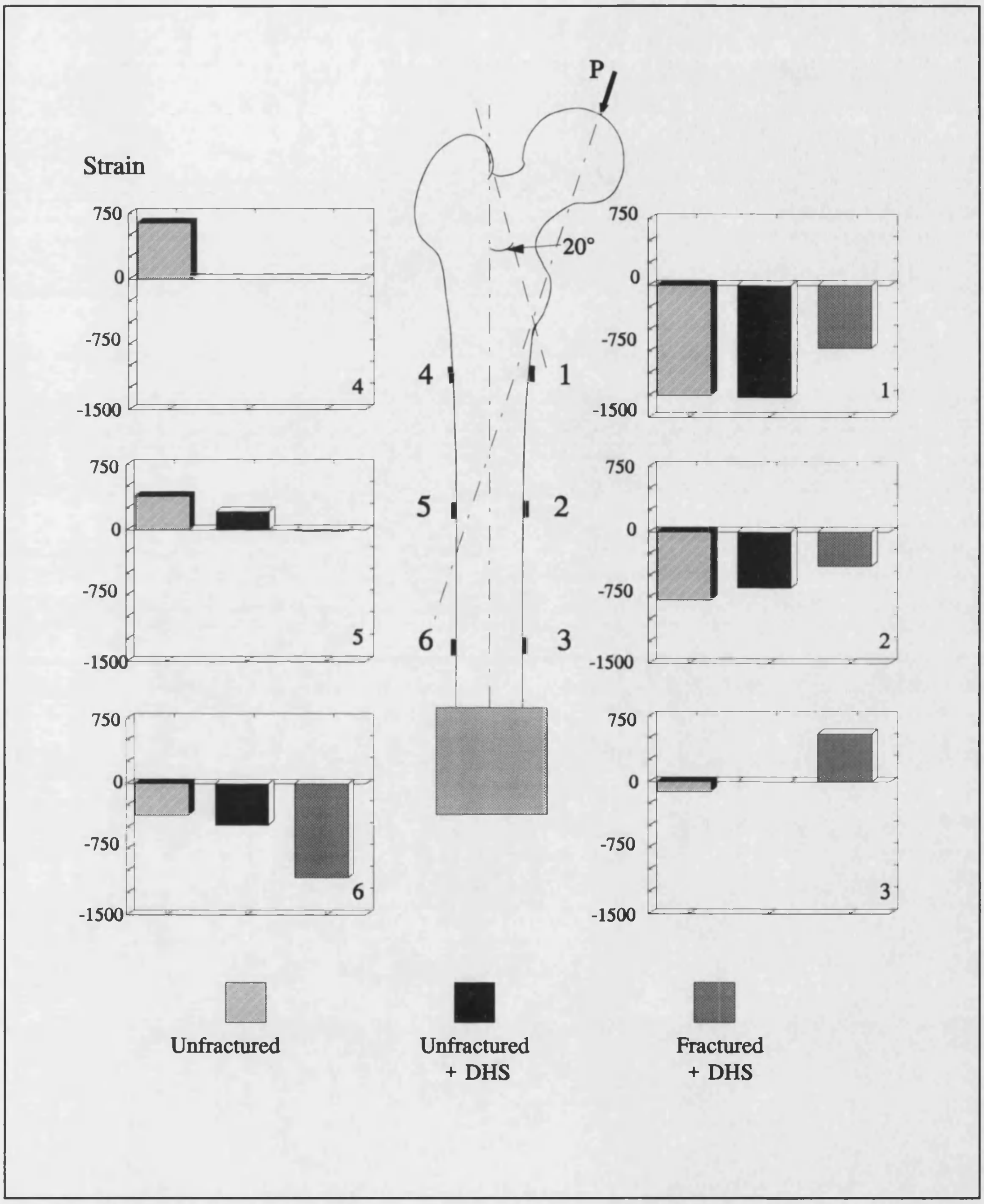

Fig 4.5 - The strain readings for Femur I at 1.8 kN under simulated fully healed and unhealed fracture configurations.

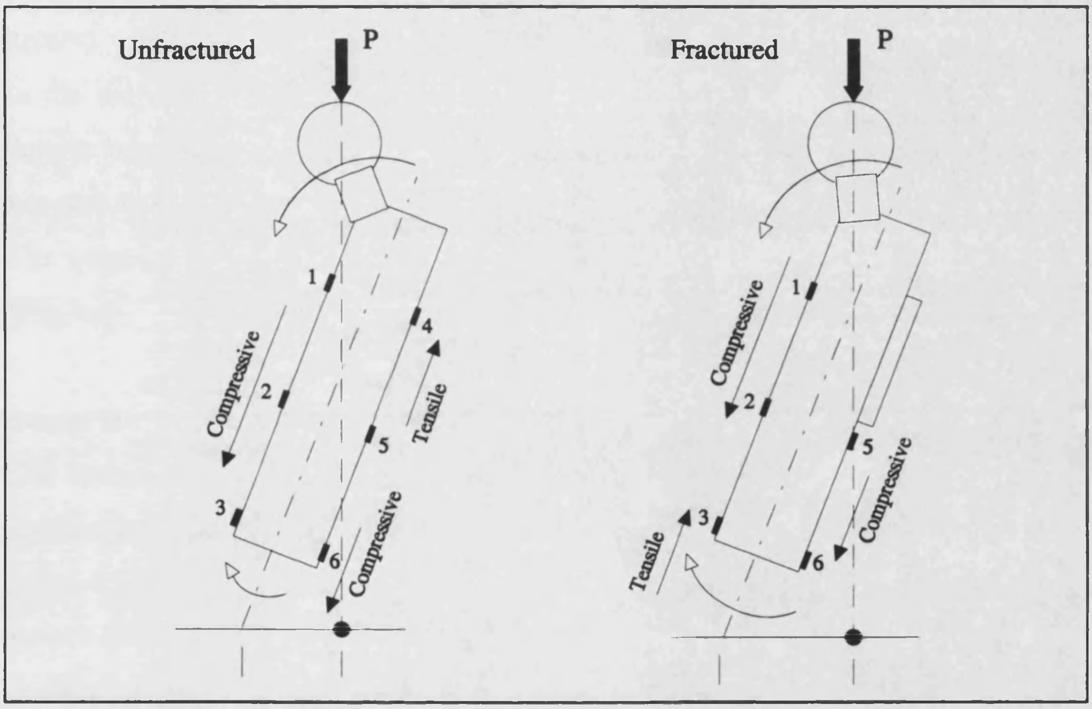

Fig 4.6 - A schematic illustration of the loading configuration of the fractured and unfractured Femur I, with DHS.

From Fig 4.4 it could be seen that the increase in strain due to the increasing load became non-linear after the DHS was implanted. Movement in the position of the lag screw during loading could not be monitored, although it was assumed to be jammed, and this may have contributed to the change in strain pattern. Displacement of the femoral head/neck alignment would also have altered the strain and subsequent linearity.

For the distal gauge on the medial surface (3) the strain had become tensile under the fractured condition. The load bearing capacity of the DHS lateral plate was transferring the load down the lateral cortex and the femur was tending to bend. This created a tensile load at the distal medial gauge. Bending of the proximal femur due to the applied load would develop reactive forces at the fixed support. A reactive couple would then develop at the base mounting point. The fractured femur had become less able to resist bending, with the resulting increase in the reactive couple. The large increase of over 500 μstrain at gauge 3 (600%) supported this assumption (Fig 4.6).

Femur II

The behaviour of the intact femur was the same as Femur I. Linear strain increases resulted in high proximal strains, reduced distally, and compressive strain recorded at gauge 6 (Fig 4.7 & 4.8). After insertion of the 12mm Gamma Nail with distal locking screws on the unfractured femur, there was almost no change in the compressive strain at the proximal medial gauge (1) and a decrease in compressive strain at gauge 2 of 178 μstrain (79%) (Appendix A: Table 8). On the lateral surface there was a decrease in the tensile strain at the proximal gauge (4) of 126 μstrain (83%) and a decrease of 20 μstrain at gauge 5 (96%).

At the distal medial gauge (3) there was an increase in compressive strain (227%), the reverse of the DHS loading condition. This suggested that the Gamma Nail was transferring more load distally under the fully healed fracture situation. At the distal lateral gauge position (6) there was a decrease in the compressive strain (46%). The increase in compression at gauge 3, in conjunction with the decrease at gauge 6, compared to the reverse affect with the DHS, was a result of the stiffer intramedullary implant and the medial position of the nail with respect to the bending axis.

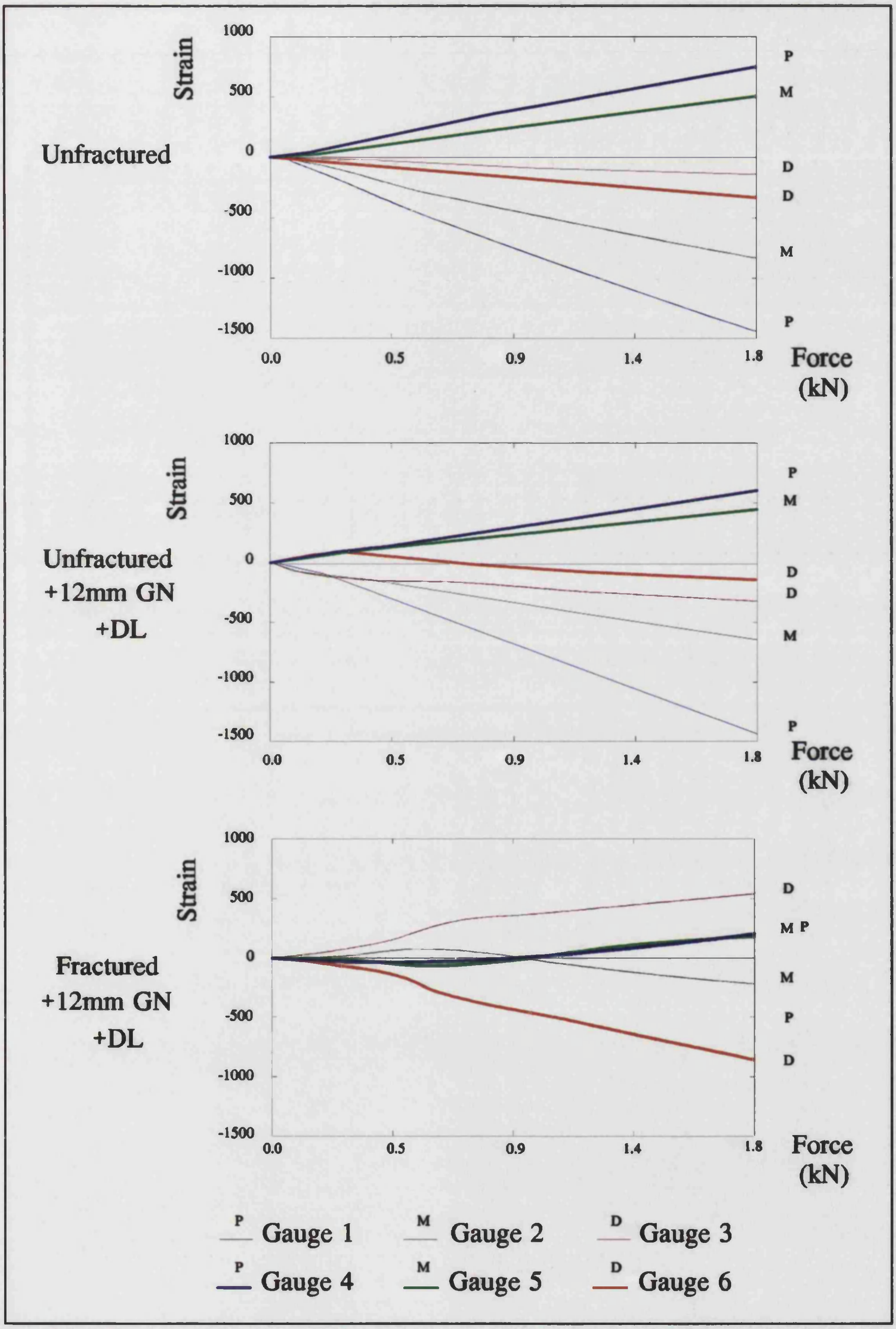

Fig 4.7 - The strain versus load characteristics for the six gauge positions on Femur II, with distal locking.

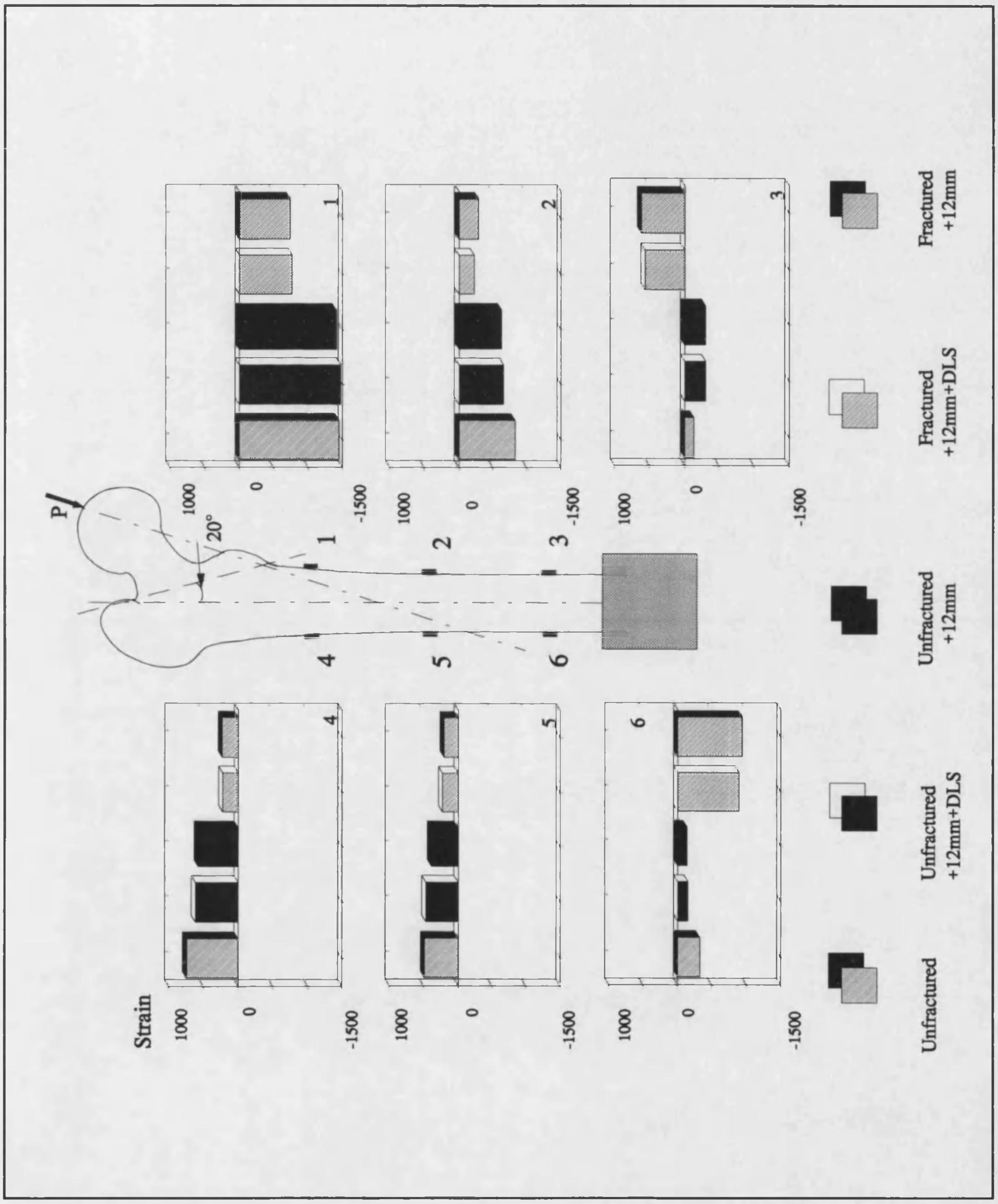

Fig 4.8 - The strain readings for Femur II at 1.8kN under simulated fully healed and unhealed fracture configurations.

The bending of the proximal femur was reduced compared to the non implanted femur or the femur with a DHS, with a corresponding reduction in the reactive couple at the base.

On the fractured femur, the compressive strain was reduced at the two proximal gauges. A reduction in compressive strain of 400 μstrain was recorded at gauge 2 (27%), with a relative decrease in tensile strain of 240 μstrain at gauge 5 (46%). The increased strength of the Gamma Nail lag screw prevented movement of the femoral head into medial displacement, which resulted in a change in the relative position of the line of load with the DHS. This ensured compression on the lateral surface beyond gauge 5. However, the two distal gauges indicated a similar pattern to Femur I with the DHS. At the lateral gauge 6, an increase in compressive strain of over 700 μstrain was recorded (270%), despite the reduction in strain with the unfractured femur. The strain on the medial surface had again become tensile.

The distal end of the Gamma Nail was positioned 45mm below gauges 5 and 2, 15mm above the distal gauges. The small diameter nail was inclined towards three point contact within the femoral canal; proximally, at the bend in the nail and at the distal tip. With the tip of the nail loading the femur directly on the lateral surface and the lack of internal support below the nail, the femur tended to bend under the applied load, as seen with the DHS. From analysis of the vertical displacement of Femur II as the load was applied, an indication of the stiffness of the femur could be established. The intact femur had a stiffness of 1184N/mm, which increased to 1243N/mm with the 12mm Gamma Nail implanted with distal locking screws. This represented a 5% increase in stiffness. This difference in stiffness could account for the change in strain between the intact and implanted femur. When the femur was fractured, the stiffness reduced to 580N/mm, a significant decrease of 51%. It was this decrease in stiffness when fractured, that contributed to the reactive bending of the femur at the mounting sleeve.

Fig 4.7 again indicated a non-linearity in the strain after the Gamma Nail was implanted. Movement in the position of the lag screw during loading could have contributed to the change in strain pattern, as observed with Femur I. Movement of the nail itself into 3 point contact within the femur could also have altered the strain.

This was supported by the graph showing the strain for the fractured femur with the locked Gamma Nail. There was a change in strain direction for the proximal gauges (2, 4 & 5) at around 500N and an increase in the strain rate for the distal gauges (3 & 6). Without X-ray facilities during the loading sequence this condition could not be verified.

The Gamma Nail was tested with and without distal locking screws for both implanted test sequences. No significant difference between the two conditions could be established from this study. The use of Sawbone femora as bone replacements, although mechanically superior, makes the surgical procedure difficult. The drilling and reaming of the composite material was not representative of real bone, with the result that the femoral canal may not have been accurately reamed. The insertion of the nail into a tight shaft would then minimise the effect of the distal locking, as seen in these results.

Femur III

Once again the behaviour of the intact femur was the same as the previous two femora, with the highest strains recorded proximally (Fig 4.9 & 4.10). When the 14mm Gamma Nail was implanted, the construct behaved in a similar manner to the 12mm Gamma Nail, with increased distal medial compression and decreased lateral compression.

When this femur was fractured, the strain at the distal gauges (3 and 6) indicated a different trend to the two previous fractured femora. The distal medial gauge (3) recorded a decrease in compression of 112 μstrain (123%) and the lateral gauge (6) an increase in compression of 200 μstrain (98%) (Appendix A: Table 9). The strain at the distal gauges had become very similar to the intact femur with no implant. As both gauges remained in compression, no bending of the shaft was occurring below the nail. The 14mm nail diameter was large enough to resist three point bending within the femoral canal better than the 12mm nail. The bending due to the applied load was therefore reduced, hence the reactive bending at the fixed mounting point. The load was transferred distally down the femur, with a load reduction proximally. The distal locking screws did not significantly alter the stain reading.

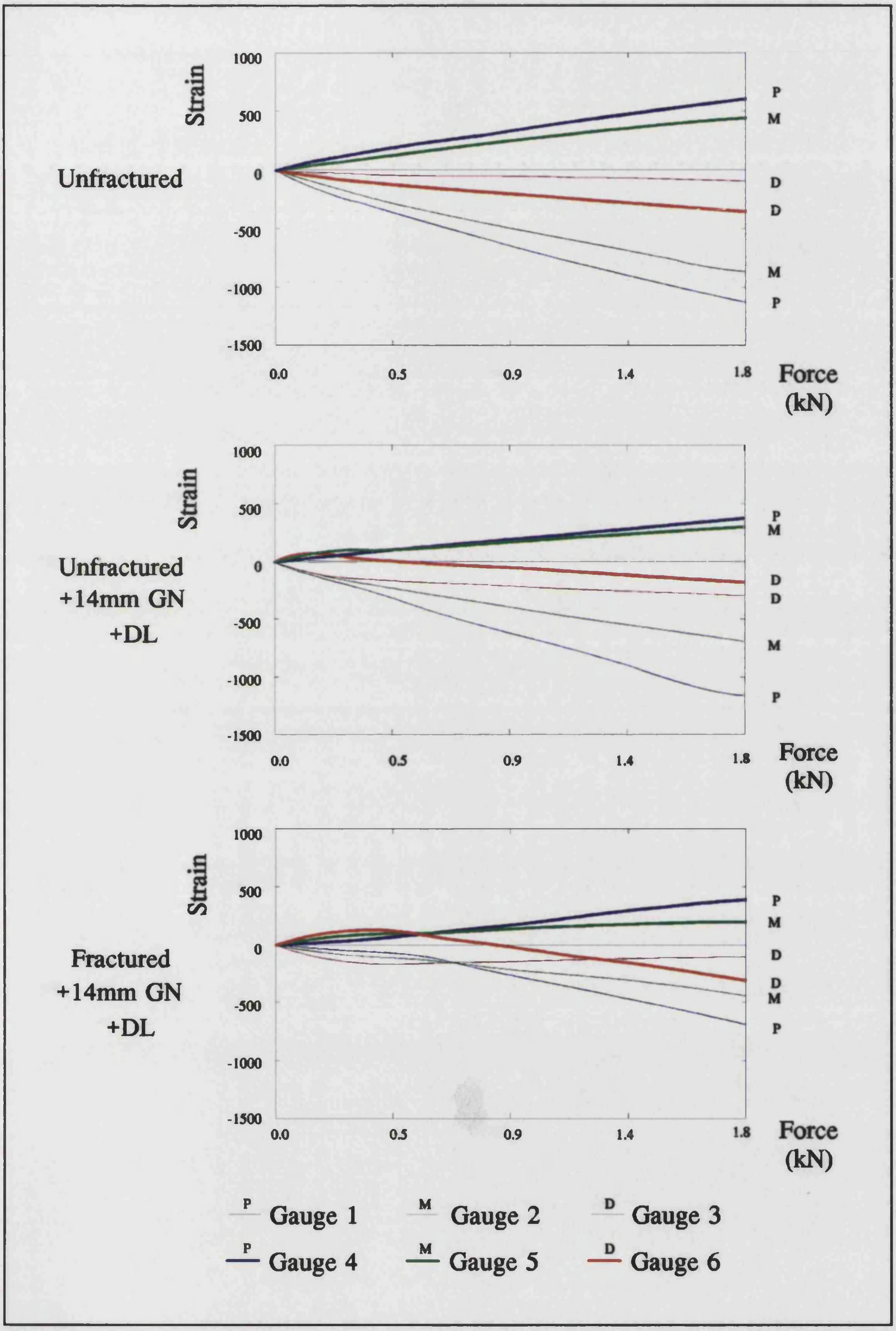

Fig 4.9 - The strain versus load characteristics at the six gauge positions on Femur III, with distal locking.

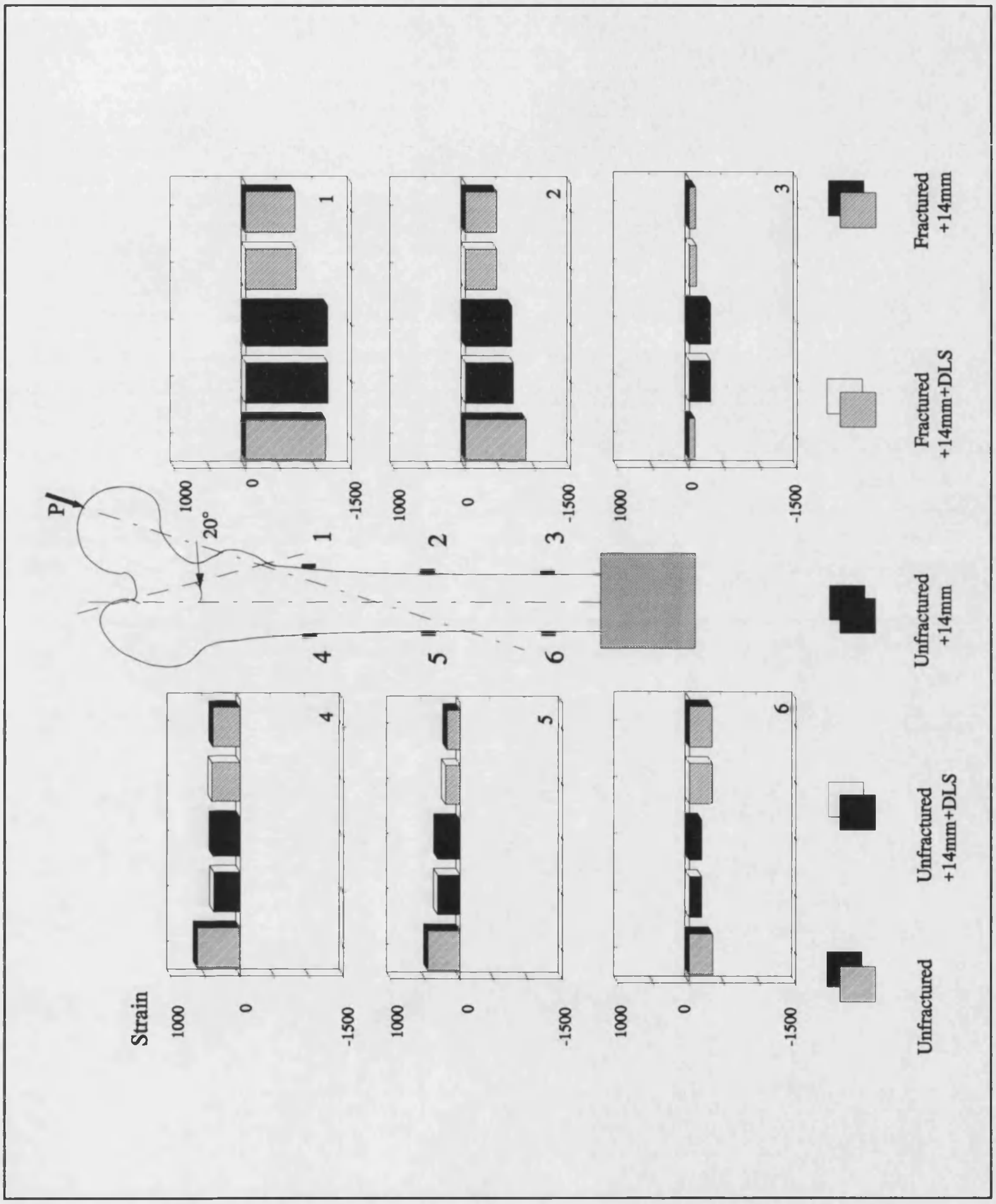

Fig 4.10 - The strain readings for femur III at 1.8kN under simulated fully healed and unhealed fracture configurations.

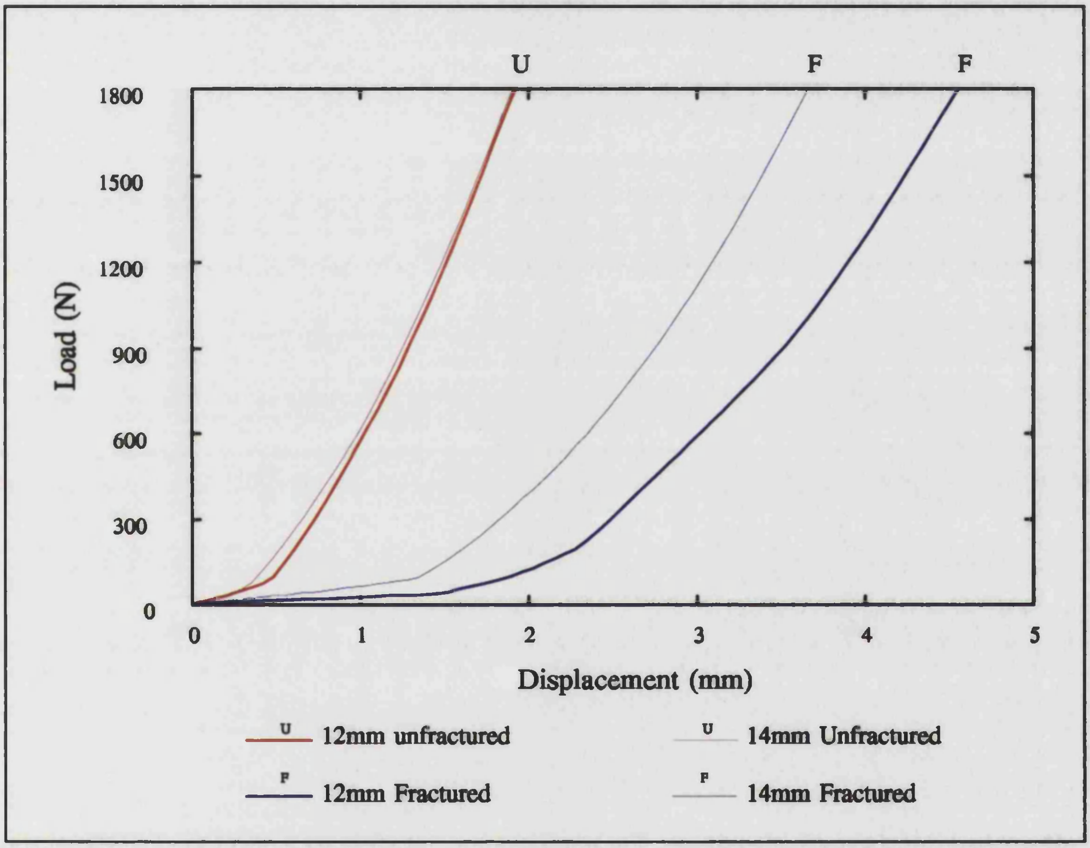

Fig 4.11 - Load versus displacement graph for the locked Gamma Nail test conditions.

Once again non-linearity in the strain readings was recorded after the Gamma Nail was implanted (Fig 4.9). The unfractured femur followed the same trend of non-linearity as femur II. With the fractured femur, there was no change in strain direction of the proximal gauges (1, 2, 4 & 5). However, the distal gauges (3 & 6) clearly changed direction at around 500N. This resulted in the lowest reading for the distal gauges in comparison the highest reading for the previous two implants.

From analysis of the vertical displacement of Femur III, the intact femur had a stiffness of 1082N/mm, which increased to 1194N/mm with the 14mm Gamma Nail implanted with distal locking screws. This represented a 10% increase in stiffness, twice the increase of the 12mm nail (Fig 4.11). When the femur was fractured, the stiffness reduced to 780N/mm, a decrease of 28%. The decrease in stiffness for the fractured femur was approximately half that calculated for the 12mm nail.

Comparison of the strain patterns for the three femora indicated that Femur III behaved differently to the other two (Fig 4.4, Fig 4.7 & Fig 4.9). With the intact femur, the maximum strain was recorded on the proximal gauges and minimal strain on the distal gauges. This pattern was consistent with the three fully healed implanted femora. With the fractured DHS and the 12mm Gamma Nail the maximum strain was recorded on the distal gauges. This did not occur with the 14mm Gamma Nail where the proximal region consistently supported the highest strain, even when the femur was fractured.

4.4 Discussion

The strain pattern identified for the intact femora was consistent with published literature (Rosenblum *et al.* (1992) and Otani *et al.* (1993)). Compression was recorded at the distal lateral gauges in both of these studies, despite variations in the mounting angles and truncated femoral lengths.

With the DHS, under conditions of unstable fracture, the load was transferred to the lateral cortex of the femur, below the plate. This resulted in an increase in the load experienced by the distal femur with a resulting decrease in the proximal load. The small diameter of the DHS lag screw did not provide sufficient rigidity at the femoral neck. This resulted in medial displacement of the femoral head due to the applied load.

In the cadaveric study (section 3) the DHS failed due to lag screw cut-out, lag screw bending and the lateral plate pulling off the femoral shaft. The conditions for lag screw bending or lag screw cut-out were investigated in section 3.5. From this study, the failure mode of cut-out was eliminated by the composite femora. The inclination for the femoral head to become medially displaced, due to the unstable fracture line, supported the likelihood of lag screw bending as a failure mode in non-osteoporotic bone.

Under fractured conditions, the highest strain was recorded distally on the lateral surface of the femur. This implied that the DHS was transferring the load distally below the plate. As a result of the medial bending of the entire construct, the most distal cortical bone screws would be under considerable loads. No loads were recorded at the gauge positioned under the proximal section of the DHS plate. The DHS barrel would form a pivot for the bending moments at the femoral neck. The distal cortical screws would therefore pull-out first due to the high bending moments experienced by them.

Under conditions of fully healed fractures, the DHS did not alter the overall strain pattern within the proximal femur. The reduction in the medial compressive strain and lateral tensile strain suggested that the implant was simply supporting a percentage of the applied load. The only increase in strain was recorded at the distal lateral gauge, just below the DHS plate. This again suggested that the DHS was supporting applied load and transferring it distally.

The Gamma Nails resisted the medial displacement of the femoral head, under unstable fractures, due to the increased rigidity of the lag screw. As a result, the line of load did not significantly alter during these tests. Unlike the DHS, the loading pattern down the lateral cortex of the femur did not alter after the simulated fracture of the femur. The 14mm Gamma nail was considerably stiffer than the 12mm under fracture conditions.

The large composite femora used in this study, have an internal shaft diameter of 15.5mm. For the 12mm Gamma Nail, the femoral shaft must be reamed to 14mm distally. Due to the nature of the foam used to fill the cavity, under fractured conditions, the 12mm nail was able to move into 3 point contact within the cavity. As a direct result of the difficulties in operative procedures on these composite femora, only one distal locking screw was used to prevent migration of the nail down the shaft. The proximal region was also slightly over reamed to aid insertion of the nail into the femur. The combination of these two factors allowed the intramedullary nail to pivot at the distal screw when distal locking was used. The problem of point contact was therefore not eliminated under these test conditions, as would be expected.

Three point contact of the nail within the femoral canal resulted in the construct bending, as experienced with the DHS. The load was transferred to the lateral surface of the femur, creating a bending moment about the nail/screw barrel. The reversal in distal medial strain recorded for the 12mm Gamma Nail, suggested that bending of the femur was taking place with the unstable fracture. The bending was inducing a reactive bending at the fixed mounting point, typical of a buckling strut. However, when the implant was in the fully healed femur, this was not evident. The loading pattern remained consistent with the intact femur. The only difference was an increase in the distal medial tension due to the increased stiffness of the implanted femur.

The 14mm Gamma nail required the femoral shaft to be reamed to 16mm distally. This resulted in reaming part of the cortical bone layer. Due to the lack of foam remaining in the composite, no movement of the nail could take place within the femoral canal. The 14mm Gamma Nail was better at resisting three point contact than the 12mm nail, with the corresponding loading patterns. When the implant was in the fully healed bone, the loading pattern was the same as the 12mm nail. There was only a 5% increase in stiffness due to the larger diameter nail. Under conditions of unstable fracture, the larger Gamma Nail supported the load proximally and transferred it distally, maintaining the stiffness of the construct and withstanding bending.

From the cadaveric study failures, the Gamma Nail failure modes consisted of lag screw cut-out and fracture of the femoral shaft. The shaft fractures occurred at the bend in the intramedullary nail in cases where no distal locking was used. When the nail was distally locked, shaft fracture occurred at the tip of the nail or around the locking screws. Once again, lag screw bending was eliminated by the composite femora. The most likely shaft fracture would occur with the 12mm Gamma Nail. The three point contact within the femoral shaft would result in regions of high stress. Shaft fracture would then occur at the points of contact when no locking screws were used. Distal locking screws themselves would introduce stress raisers which could lead to shaft failure under adverse loading conditions.

4.5 Closure

The cadaveric study highlighted lag screw cut-out as the most likely failure mode for both the DHS and the Gamma Nail. The other failure modes reported in the clinical literature and recreated in the cadaveric analysis, were lag screw bending and femoral shaft failures.

Lag screw bending was a failure mode with the DHS lag screw only. In this study the Gamma Nail lag screw provided superior support within the femoral neck. The other failure mode reported for the DHS was the lateral plate pulling off the femoral shaft. The movement of the femoral head into medial displacement with the DHS altered the line of load bearing relative to the femoral shaft. The reduction in stiffness of the fractured shaft resulted in increased distal loading due to buckling of the fractured construct. The DHS appeared to transfer the load down the lateral surface of the femur. The resulting loads on the cortical bone screws due to the bending, would in turn lead to the screws pulling out of the shaft.

The Gamma Nail failure modes of shaft fractures occurred at the bend in the intramedullary nail, at the tip of the nail or around the locking screws. This study suggested that these failure modes would occur due to three point contact of the Gamma Nail within the femoral canal. The was indicated by the 12mm Gamma Nail, where increased distal loading was again recorded with the unstable fracture. The large diameter composite femur used in the testing was better suited to the larger 14mm intramedullary nail, where the nail was not able to move within the shaft. The shaft failure modes recorded in the cadaveric study could all be due to three point contact of the nail. This was also a cause reported in the clinical literature, for the shaft failure mode (Williams *et al.* (1992)). The intertrochanteric tests did not use locking screws. The subtrochanteric tests represented an inherently unstable fracture where movement of the fracture sections with respect to one another could lead to point contact of the nail.

Accurate surgical protocol would reduce the risk of failure with the intramedullary nail. The DHS is a mechanically weaker design. Both these factors should be significant when selecting a sliding hip screw. The cadaveric study indicated both implants were more likely to fail due to lag screw cut-out. Therefore, before either of these design criteria need to be considered in more detail, analysis of the sliding characteristics must be completed.

Chapter 5

BIOMECHANICAL DYNAMIC LOADING STUDY

The cadaveric study described in chapter 3 highlighted the problem of screw cut-out as the most likely failure mode with both the DHS and the Gamma Nail. This failure mode was particularly common in clinical practice with the fixed one piece implants that were the predecessors to the sliding devices. The sliding lag screw was initially used in an attempt to overcome this problem, sliding within the barrel as the fracture site reduces, transferring the load over a larger area. It could therefore be assumed that in the clinical situation, the failure may occur if the lag screw jams within the barrel and the sliding implant then acts as a one piece device.

In order to highlight the potential conditions of the lag screw jamming within the barrel, an investigation was undertaken to determine the optimum conditions under which the lag screw slides. The applied loads used throughout these biomechanical experiments were based on those previously used by Kyle *et al.*(1980), to represent the *in vivo* loading in the clinical situation. However, no previous published studies have examined the loads associated with sliding hip screws under conditions of dynamic flexion.

A series of tests were devised to establish the influence of a range of individual loading parameters on the sliding performance of the Gamma Nail and DHS, under static and dynamic loading conditions.

5.1 Test Rig Design

Dynamic Flexion Test Rig

A motorised test rig was designed and developed (Fig 5.1), capable of simulating both static and dynamic loading cycle conditions at 4 ranges of flexion, (0°, 20°, 30° and 40°) thus representing a range of gaits possible after an operative procedure.

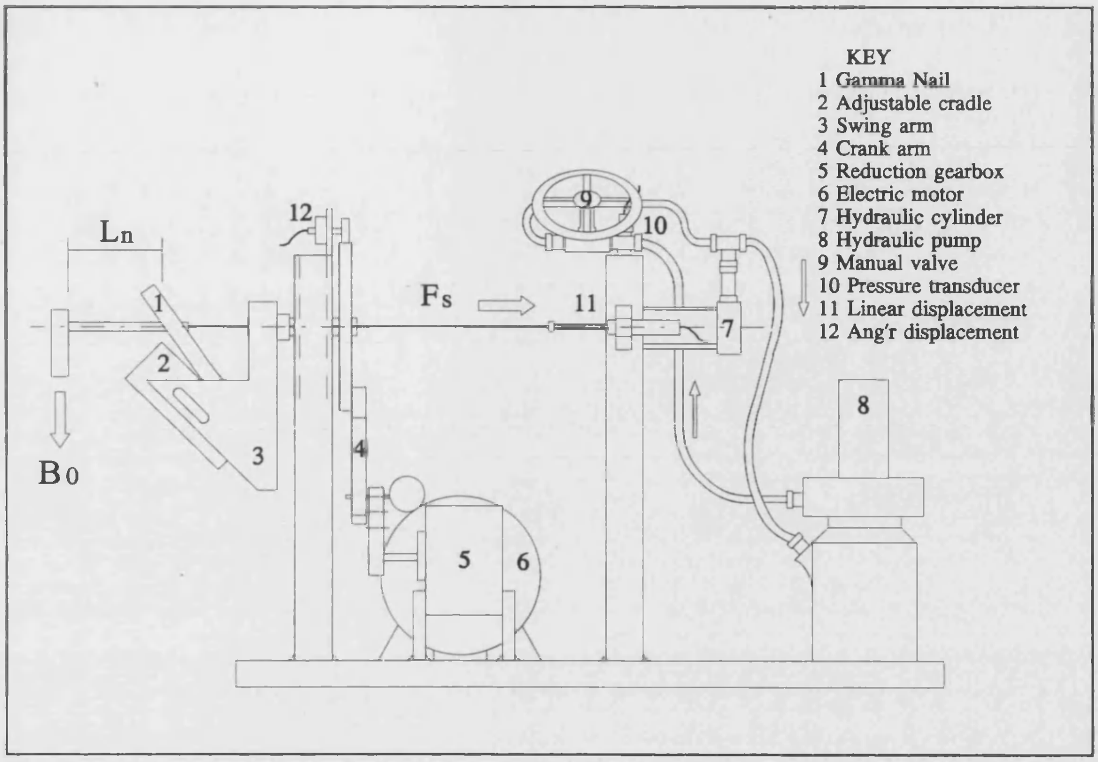

Fig 5.1 - Dynamic flexion test rig.

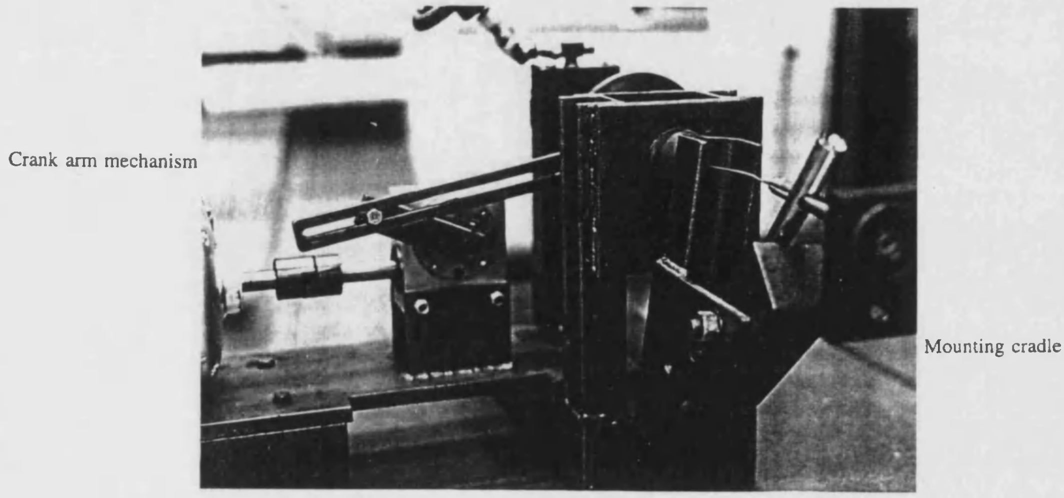

Fig 5.2 - Photograph showing the flexion mechanism on the test rig.

No published studies have examined the performance of sliding hip screws under dynamic flexion conditions. The rig was a development of a simple static loading test rig.

The sliding screws were mounted in an adjustable cradle on a swing arm, positioned with the axis of rotation coincident with the axis of the lag screw. The swing arm was driven by an adjustable length crank arm coupled to an electric motor, via a reduction gearbox, such that it could be rotated through any cycle at 1Hz. The adjustable crank arm provided the mechanical system of varying the flexion angle (Fig 5.2). A fixed vertical load was supported from the threaded end of the screw, representing the vertical component of bodyweight (B_0). A variable axial load was applied along the axis of the lag screw (F_s), by a cable attached to the rear of the screw, connected to a linear hydraulic actuator. The use of an hydraulic actuator to apply the axial load meant that a simple manual valve could be employed to gradually increase the applied force at a variety of loading rates.

The axial load applied was recorded by a pressure transducer connected across the hydraulic actuator and the screw displacement was simultaneously recorded by a linear displacement transducer parallel to the piston. The angle of flexion and extension was recorded as the angle of rotation of the swing arm, using a rotary displacement transducer. The readings were recorded electronically, at a sampling rate of 30Hz using a PC based data acquisition system, fed directly into a spreadsheet. The point of initiation of slip of the screw was identified by a macro within the data spreadsheet.

5.2 Test Parameters

Sliding hip screws are manufactured with a range of angles between the lag screw and the nail/plate, the implant angle (ß). The angle of the implant utilised by surgeons is largely dependent on their clinical judgement. Some clinicians use one implant angle in all operative procedures, independent of the femoral geometry. An alternative protocol is to use the implant angle that is closest to the anatomical angle of the femoral neck. The weight and size of the patient in the clinical situation determines the loads experienced by the implants *in vivo*. The typical case of an elderly lady with a small frame and a relatively light bodyweight would not develop excessive forces through the implant and the distance from the axis of the femur to the cortical bone at the head of the femur would be short. This could be represented by altering the static vertical load applied to the end of the lag screw and the length of the screw protruding from the barrel.

Within the development of the initial test rig, each parameter was capable of being altered individually. A range of currently available nail and plate angles for the two implants were included in the study:

- i) Gamma Nail angles of 125°, 130°, 135° and 140°
- ii) DHS plate angles of 135°, 140°, 145° and 150°.

For each test sequence three significant parameters were fixed (Fig 5.3):

- i) The screw length protruding from the barrel (L_n)
- ii) The static vertical load suspended from the screw (B_0) (maximum load determined by the equation $B_0 = 465 \sin(159° - \beta)$)
- iii) The dynamic/static angle of flexion

Each individual test cycle therefore consisted of presetting the test parameters and gradually increasing the axial load until initiation of lag screw sliding was identified from the linear transducer. Six individual tests were completed for each test configuration. The standard deviations are indicated on each bar chart showing the mean results. The sliding force required by each test was determined from the recorded axial force at the point of initial displacement of the screw. This can be seen from a typical set of data recorded from the three transducers on the dynamic flexion test rig (Fig 5.4).

Kyle *et al.* (1980) detailed the correlation between the sliding force and the coefficient of friction. They stated that for sliding of an implant to occur, the axial component of force applied must exceed the load required to initiate sliding, which is itself governed by the perpendicular component of load, the actual coefficient of friction between the sliding surfaces and the length of the screw protruding from the barrel.

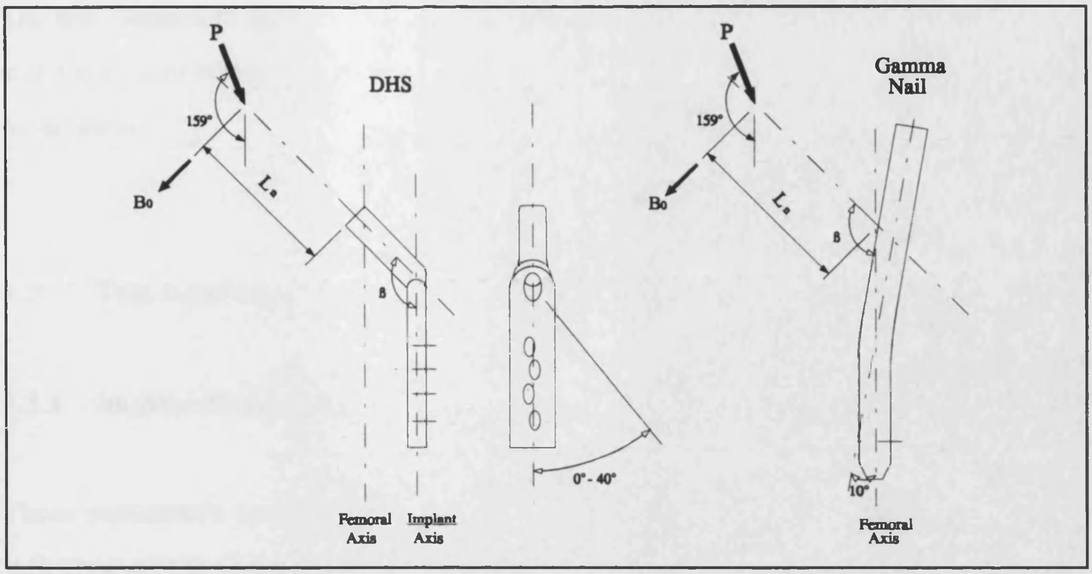

Fig 5.3 - Illustration of the variable parameters required in each test configuration for the two implants tested.

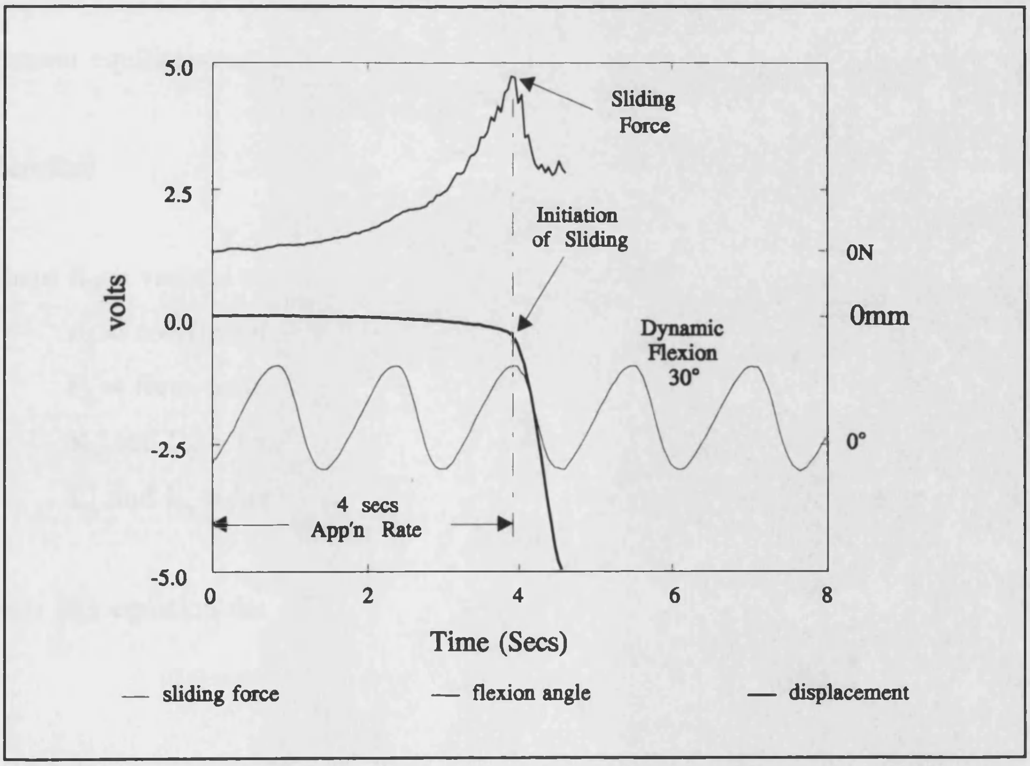

Fig 5.4 - A typical data set for the three transducers under conditions of dynamic flexion.

The test sequences were designed to study each of the individual parameters initially and then complement these simple tests with calculated combinations of the same parameters.

5.3 Test Sequences

5.3.1 Implant Parameters

Three parameters were tested initially in individual test sequences, to determine the influence on the sliding force due to each one. From conditions of static equilibrium for the lag screw at the point of initiation of sliding, an equation for the coefficient of friction could be established (Fig 5.5). It was assumed that the sliding clearances within the barrel of the implants would cause the lag screw to pivot within the barrel, resulting in maximum loading of the lag screw at the points of exit from the barrel (R_1 and R_2).

Force equilibrium: $B_0 = R_1 - R_2$

$F_s = \mu_0 R_1 + \mu_0 R_2$

Moment equilibrium: $B_0 L_n = R_2 L_b$

Therefore $\mu_0 = (F_s/B_0) / (1 + 2L_n/L_b)$ (Kyle *et al.* (1980))

Where B_0 = vertical component of body weight

μ_0 = coefficient of friction

F_s = force to initiate sliding - sliding force

R_1 and R_2 = barrel reaction forces

L_n and L_b = lag screw lengths

From this equation the parameters L_n, B_0 and L_b were tested.

5.3.1.1 Screw Length (L_n)

Method

The length of the lag screw *in vivo* is determined by the anatomical dimensions of the femora and as such is a non-variable parameter in the clinical situation. As the perpendicular distance from the tip of the lag screw to the vertical axis of the nail or plate is a constant, the higher angled implants will require longer lag screw lengths and vice versa. Larger femora will also clearly require longer screw lengths.

The tests were completed on a 135° implant angle only, at flexion angles of 0° static and 30° dynamic flexion. A static vertical load of 190N was applied with both implants. The lag screw lengths tested ranged from 90mm to 105mm (increment 5mm), with the Gamma Nail and from 55mm to 70mm with the DHS. The different range of lengths used was dictated by the design of the implants themselves. Six individual tests were performed for each test sequence.

Results

The results suggested that a linear relationship existed between the screw length protruding from the barrel and the axial sliding force required for both implants (Appendix A: Table 10 & Table 11). The longer screw lengths required a greater axial force to initiate sliding and the force required under dynamic conditions was less than for the static conditions.

For the Gamma Nail, a 15% increase in screw length resulted in an 8% increase in sliding force for both the static and dynamic loading conditions (Fig 5.6). The relative increase in lag screw length for the DHS was 27%. The resulting increases in sliding force was 37% under static loading and 27% under dynamic conditions. By interpolating the length back to 15% for the DHS, the increase in sliding force was 21% under static loading and only 7% under dynamic loading. These results imply that the effect of the lag screw length on the sliding force is more significant with the DHS under static conditions.

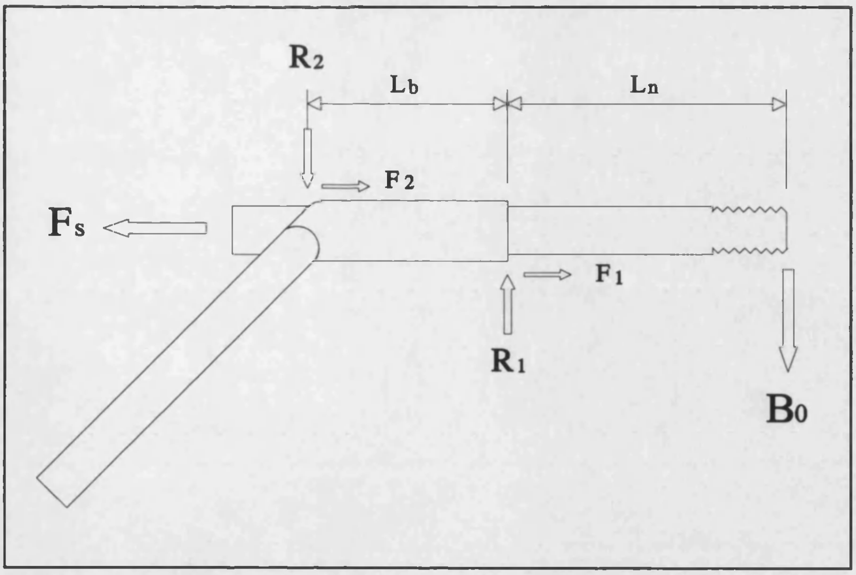

Fig 5.5 - Illustration showing the reaction forces at the DHS barrel in relation to barrel length and lag screw length.

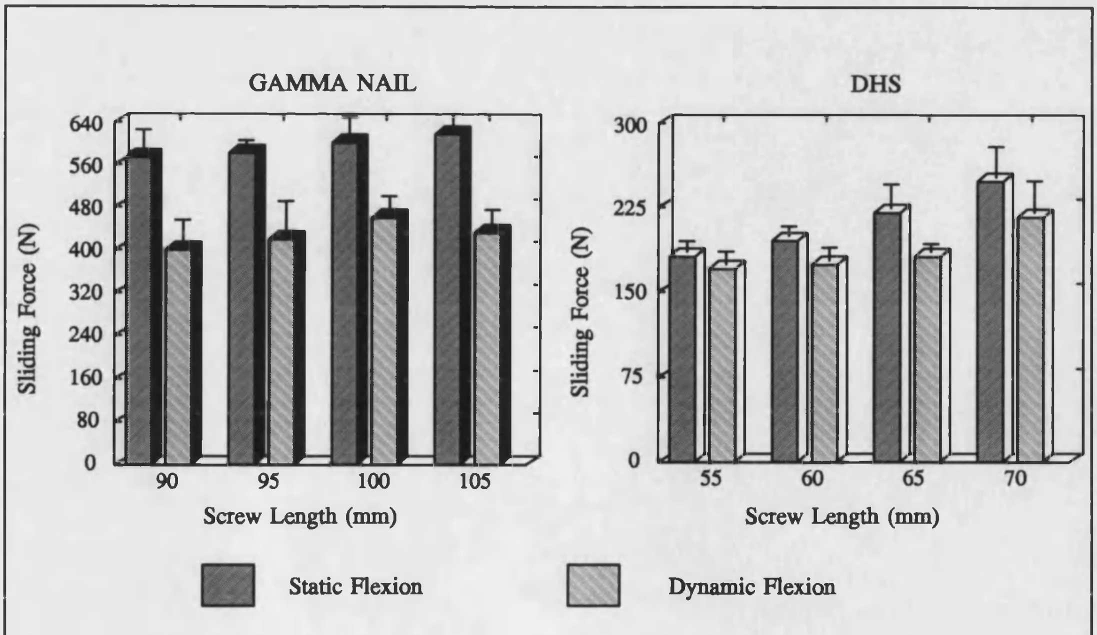

Fig 5.6 - The mean sliding force required for a range of lag screw lengths under dynamic and static flexion conditions for the Gamma Nail and DHS, from 96 tests.

5.3.1.2 Static Vertical Load (B_0)

Method

Once again 135° implant angles were tested for both devices, with lag screw lengths of 105mm for the Gamma Nail and 70mm for the DHS, both at 0° static flexion. The majority of test sequences within this study employed the maximum static vertical load calculated from the weight of a 70kg person, determined by the implant angle. This test took this load of 190N as the highest value, reducing it to 30N incrementally.

Results

A linear trend between the axial sliding force and the static vertical load was exhibited under static loading conditions with both implants (Fig 5.7). An 84% reduction in load for the Gamma Nail resulted in a reduction of around 69% in the sliding force (Appendix A: Table 12). For a similar reduction in load for the DHS the sliding force was reduced by around 71%. The material properties of the DHS lag screw differed from the Gamma Nail, which resulted in more wear of the sliding surfaces apparent at the higher loads, causing some irregularities in the linear behaviour of the DHS (Appendix A: Table 13).

In the study reported by Kyle *et al.*(1980), different implant angles were simply represented by altering the vertical component of load from the calculated value for a standard 135° implant, to the calculated perpendicular component associated with a different angle. Their results are thus an indication of the effects of the vertical component of load or bodyweight, rather than the corresponding implant angle, as was concluded. The intramedullary nails in particular have a different barrel length associated with each implant angle, which would alter the reaction forces at the barrel and the corresponding resistance to sliding.

5.3.1.3 Barrel Length (L_b)

Method

This test series was undertaken on the DHS only, comparing two different barrel lengths. The DHS is currently manufactured with the standard 35mm barrel or a shorter 25mm barrel, recommended for insertion into small femoral heads.

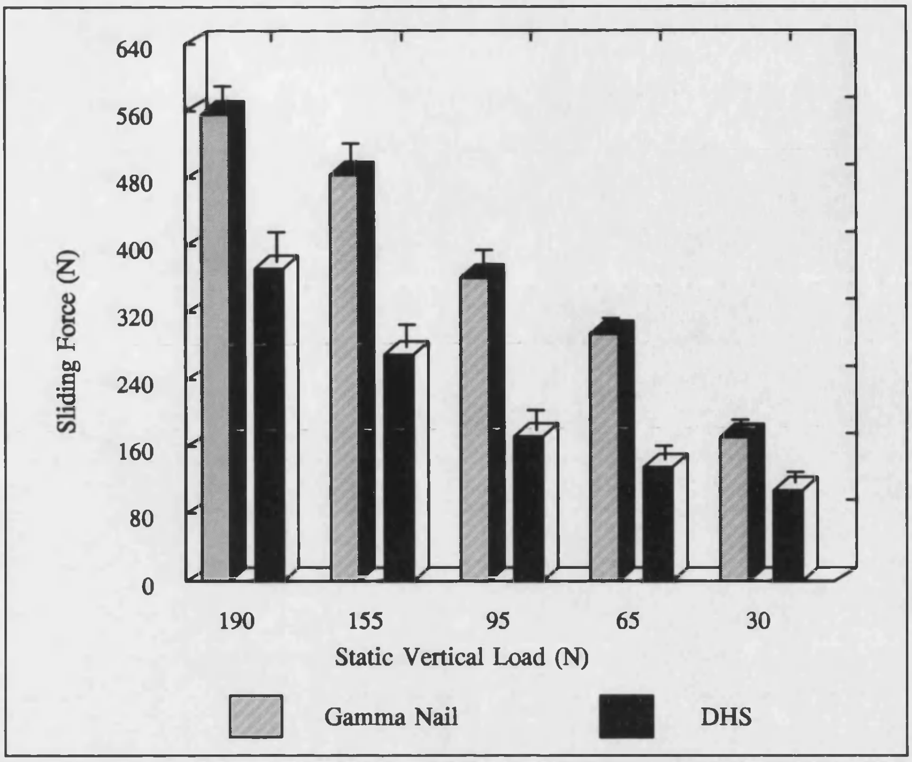

Fig 5.7 - The mean sliding forces required for a range of static vertical loads under 0° static flexion conditions, from 60 tests.

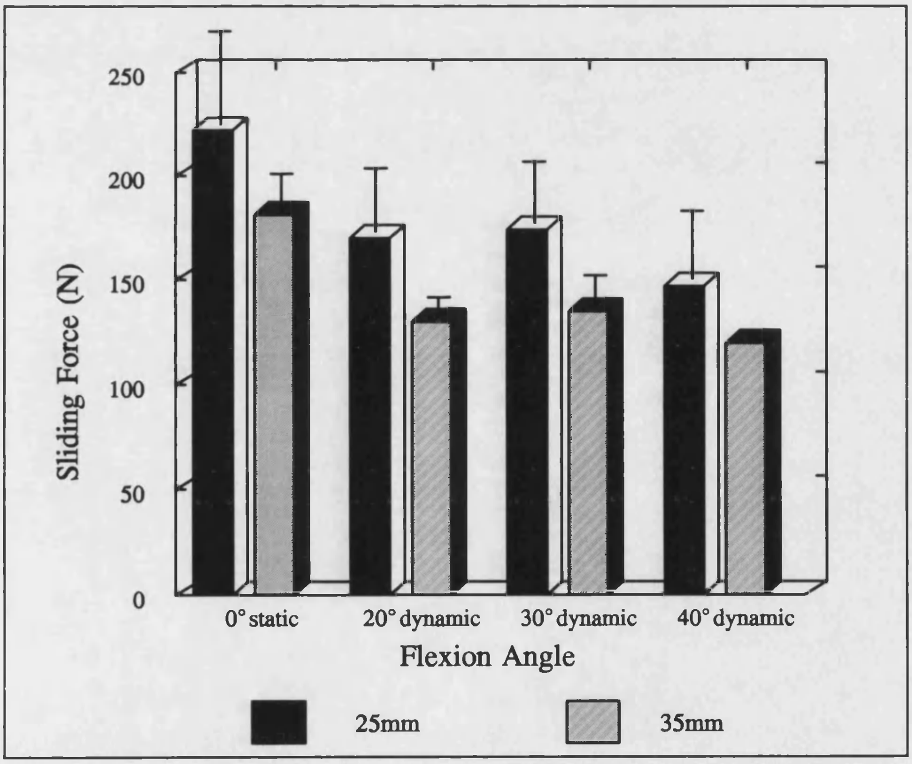

Fig 5.8 - The mean sliding forces for the DHS with two barrel lengths under static and dynamic flexion conditions, from 48 tests.

A 135° implant angle was used in both cases, with a 70mm lag screw length and a 95N static vertical load. The reduced static vertical load used throughout this test sequence was to minimise some of the lag screw damage that occurs as the screw slides within the barrel. Flexion angles of 0° static and 20°, 30°and 40° dynamic were tested.

Results

In this test sequence, the shorter barrel length required an axial sliding force around 23% greater under both static loading conditions and maximum dynamic flexion conditions (Fig 5.8) (Appendix A: Table 14 & Table 15).

From the conditions of static equilibrium, the reaction force (R_1) at the point of exit from the barrel highlighted an increase in force of 27% between the two DHS barrel lengths under the loading conditions used (section 5.3.2).

$$R_1 = 285N\ (35mm) \qquad\qquad R_1 = 361N\ (25mm)$$

The calculated barrel length of the 135° Gamma Nail is 10.63mm. The resulting barrel reaction force under the same loading conditions would be 721N, a significant increase over either of the DHS barrel lengths. This suggests that the Gamma Nail would require greater axial load to overcome the barrel reaction forces.

5.3.2 Calculated Parameters

Testing the effect of individual changes in one parameter clearly does not represent any clinical situation. An understanding of the combined effect of the three parameters *in vivo* was determined by completing comparative test sequences on combined parameters.

The equation for the apparent coefficient of friction between the lag screw and the barrel is dependant on the screw length extending from the barrel (L_n) and the parallel and perpendicular forces (B_0 and F_s) (Section 5.3.1).

$$\mu_0 = (F_s/B_0) / (1 + 2L_n/L_b)$$

The reaction force (R_1) at the point of exit from the barrel was thus dependent on the static vertical force (B_0) and the screw length within and protruding from the barrel (L_b and L_n)

$$R_1 = B_0(1 + L_n/L_b)$$

The bending moment (M) at the point of exit of the barrel was dependent on the lag screw length (L_n) and the static vertical load (B_0), shown in the simple bending equation. This equation does not account for different barrel lengths.

$$M = B_0L_n$$

A sequence of tests was therefore undertaken with equal reaction forces (R_1) for the two implants, and a second sequence with equal bending moments (M).

5.3.2.1 Equal Reaction Force (R_1)

Method

For the Gamma Nail and the DHS to exhibit an equal reaction force at the point of exit of the barrel, the values for the screw length (L_n) and the static vertical load (B_0) were calculated accordingly for the different barrel lengths.

This test compared the Gamma Nail and the DHS with an equal reaction force of 570N. This was the reaction force for a 135°, 35mm barrel length DHS with a 70mm lag screw length and a static vertical load of 190N. The resulting 135° Gamma Nail conditions required a screw length of 100mm with a vertical load 55N, with a barrel length of 10.63mm. The test were completed at 0° static flexion and dynamic flexion angles of 20°, 30° and 40°.

Results

In the static condition the axial sliding force for the DHS was 17% greater than the Gamma Nail (Fig 5.9). The coefficient of static friction for the two screws was calculated to be 0.242 and 0.176 respectively (Appendix A: Table 16). This was in agreement with the values quoted by Kyle *et al.* (1980) of 0.199 to 0.238 for a range of sliding hip screws.

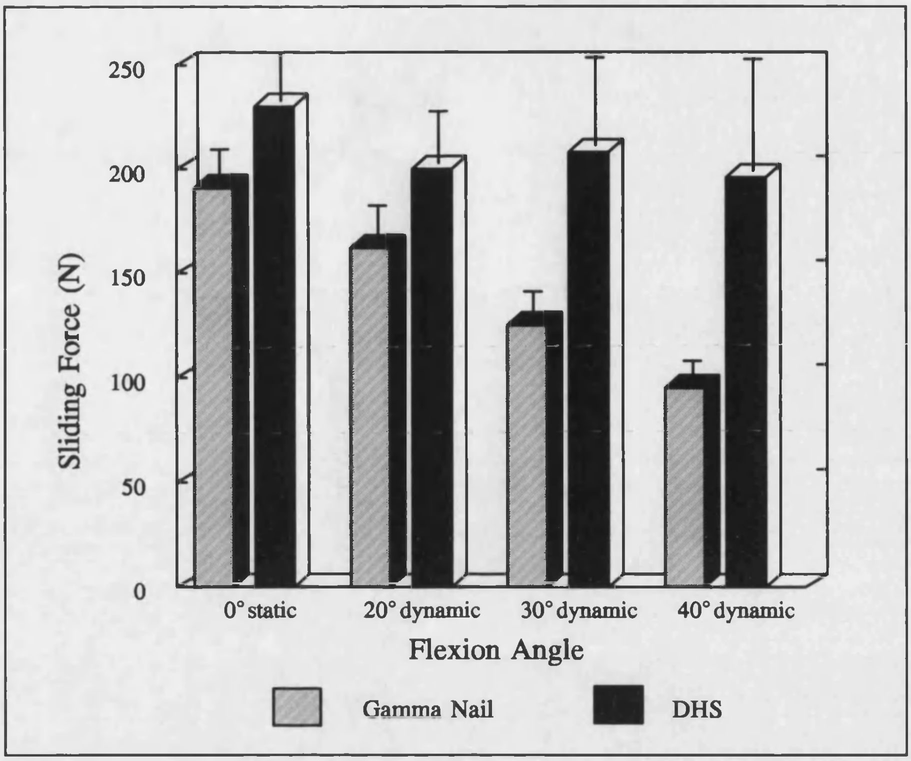

Fig 5.9 - The mean sliding forces for a known reaction force under static and dynamic flexion for both implants, from 48 tests.

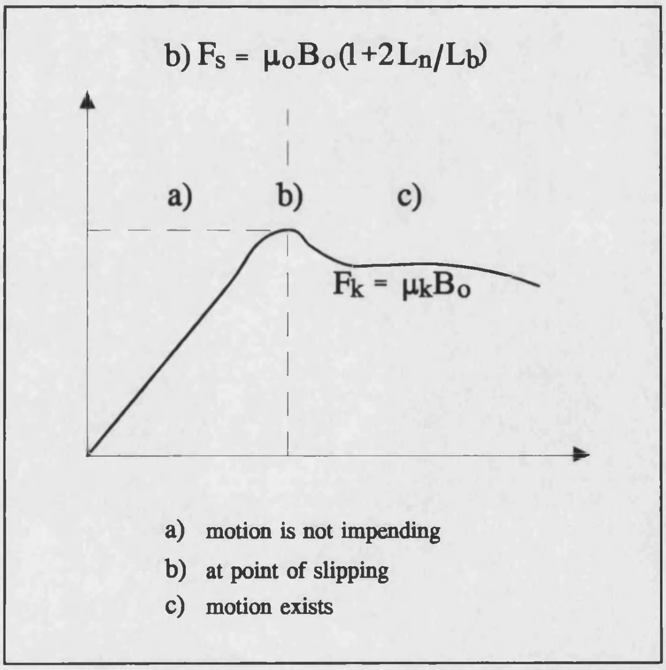

Fig 5.10 - An example of the frictional properties of metal to metal surface contact.

However, under dynamic flexion conditions, different characteristics for the two devices were evident. The sliding forces for the Gamma Nail reduced by around 50% under dynamic conditions, with the lowest force required at the maximum angle of flexion.

The DHS screw by contrast displayed a minimal reduction in force of 15% between the static and maximum dynamic condition. This implied that the kinetic friction condition, initiated by the rotational movement of the lag screw, was considerably lower for the Gamma Nail. Coefficients of friction of 0.21 were calculated for the DHS compared to 0.088 for the Gamma Nail (Fig 5.10), a minimal decrease in the friction coefficient for the DHS but a reduction of over 50% for the Gamma Nail.

5.3.2.2 Equal Bending Moments (M)

Method

The same conditions for the DHS were used as in the reaction force test, for a 135° implant angle with a 70mm lag screw length and a 190N static vertical load (where R_1 = 570N). The 135° Gamma Nail was set up for a corresponding bending moment of 13.23Nm, with a 95mm lag screw length and a 140N vertical load (where R_1 = 1391.2N). Tests were completed for the 0° static flexion condition only.

Results

The relationship between the dynamic and static test condition was assumed to follow the same pattern as the previous results, so only the static condition was represented in this test sequence. The Gamma Nail required a sliding force of 335N, approximately 50% greater than the DHS, at 221N. The reaction forces resulting from these conditions indicated that the Gamma Nail lag screw experienced a far higher reaction force at the point of exit from the barrel (Appendix A: Table 17). This suggested that it was the reaction force experienced at the barrel that determined the sliding characteristics of the implant, due to the friction component.

5.3.3 Movement Parameters

Dynamic and static flexion conditions have been used throughout the preceding test sequences. A sequence of tests were completed to specifically look at the effect of a range of dynamic flexion cycles on the axial sliding force (F_s). These were then compared to an equivalent range of static flexion cycles, where the adjustable cradle is held at the maximum flexion angle for the duration of the test. A third test sequence was completed to examine the effect of the rate of load application, designed to be a simulation of different movement speeds.

5.3.3.1 Dynamic Flexion

Method

Each implant was tested at 0° static, followed by 20°, 30° and 40° dynamic flexion. A range of implant angles (ß) were tested including 125°, 130°, 135° and 140° Gamma Nails and 135°, 140°, 145° and 150° DHS, the static vertical load for each condition being calculated from the implant angle for an assumed bodyweight of 70kg. Both implants were tested at two lag screw lengths; 95mm and 105mm for the Gamma Nail and 60mm and 70mm for the DHS.

Results

As experienced in the previous test sequences, it was established that significantly higher loads were required to initiate sliding at 0° static flexion compared to the dynamic angles of flexion (Fig 5.11) for both implant designs. The implant angle also influenced the sliding force, the greater angles requiring a reduced axial force.

For the Gamma Nail, considering the effect of the implant angles, the greater nail angles required lower forces to initiate sliding. Comparing the 140° and 125° nail, this decrease ranged from 18% under conditions of static loading to 55% at the maximum dynamic flexion. For each implant angle, as the dynamic angle of flexion increased the sliding force reduced, the significance of which was dependent on the implant angle. Comparing the 40° dynamic angle of flexion with the 0° static case, the axial sliding force was reduced in the order of 40% with the 125° nail, rising to as much as 68% in the case of the 140° nail. (Appendix A: Table 18 & Table 19). As expected the reduction in lag screw length caused a corresponding reduction in all the required axial sliding forces.

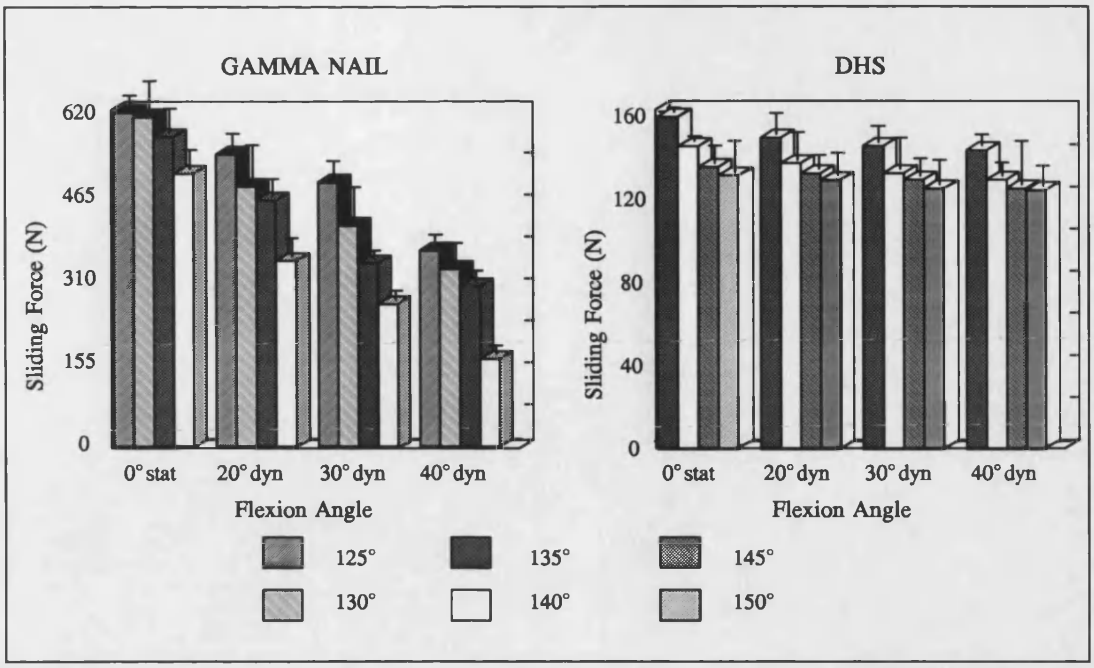

Fig 5.11 - The mean sliding forces for a range of implant angles (L_n max), under static and dynamic flexion for both implants, from 192 tests.

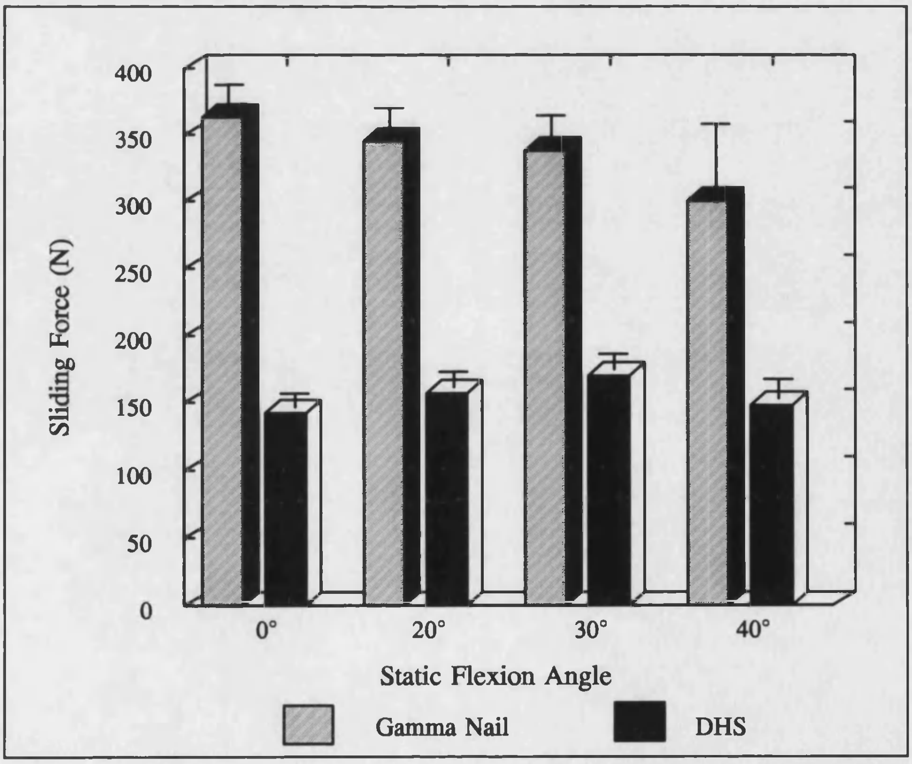

Fig 5.12 - The mean sliding forces under static flexion angles with reduced static vertical loads for both implants, from 48 tests.

The conditions represented by the DHS parameters were not equivalent to those tested with the Gamma Nail with the result that the forces required to initiate sliding were considerably lower under all conditions for the DHS. Once again comparing the 150° and 135° plate angles, the sliding force reductions ranged from 13% to 17% for the static loading and dynamic flexion cycles. Comparing the maximum dynamic flexion with the static flexion, the reduction in sliding force was always much less significant with DHS, in the order of 10% for the 135° plate and 6% for the 150° plate.

Comparing the two 135° implant angles, at 0° static the Gamma Nail required forces around three times higher than the DHS. At 40° dynamic flexion this increase was reduced to less than twice the value (Appendix A: Table 20 & Table 21). This reconfirms the results shown in the sequence of tests comparing the implants under equivalent reaction forces, that the Gamma Nail is more significantly affected by dynamic flexion that the DHS.

For both implants the point of initiation of sliding occurred at the point of maximum flexion under dynamic conditions.

5.3.3.2 Static Flexion

Method

A static test involved maintaining the cradle statically at the selected angle of flexion corresponding to maximum flexion angles from the previous dynamic tests. For the Gamma Nail, a 135° implant was tested at 0°, 20°, 30° and 40° static flexion angles with the same two lag screw lengths of 105mm and 95mm. Two static vertical loads were tested, the standard 190N and a reduced load of 95N. With the 135° DHS, lag screw lengths of 70mm and 60mm were tested at the reduced static vertical load of 95N only.

Results

For the Gamma Nail under static conditions the sliding force once again decreased as the angle of flexion increased (Fig 5.12). The reduction in force was not as significant as dynamic flexion produced, with a reduction of around 12% between 0° and 40° (Appendix A: Table 22 & Table 23).

Under 0° static conditions the load bearing surface of the lag screw was along the groove, through the set screw. As the nail was rotated the load bearing surface transferred onto the curved lag screw circumferential surface, creating a sliding surface with less resistance. This could be assumed from these static results due to the small reduction in sliding force. This was also supported by the dynamic flexion results, as the lag screw was observed to begin to slide at the point of maximum dynamic flexion, hence at the position of least sliding resistance.

The DHS showed a minimal variation in sliding force as the static flexion angle was increased. However, in contrast to the Gamma Nail performance, there was a small increase in the sliding force of around 4%, between the 0° static and 40° static loading conditions. The load bearing surface of the DHS at 0° was the curved circumference of the lag screw, similar to that of the Gamma Nail at 40° flexion. As the screw was rotated the flats along the length of the lag screw started to bear some of the load, the 'corner' between the two surfaces creating a considerable amount of resistance. This increase in sliding force could account for the considerably smaller decrease in sliding force identified with the DHS under dynamic loading conditions (Appendix A: Table 24).

5.3.3.3 Loading Application Rate

Method

Three different loading rates were employed; quasi-static, intermediate and "fast", the rates being characterised by the time taken from the initial application of load to initiation of sliding, typically 8 seconds, 4 seconds and 2 seconds for the three rates. The loading rate was controlled by a manually operated needle valve regulating the flow to the hydraulic loading cylinder. Once again a 135° Gamma Nail, with a 95mm screw length was tested with a reduced static vertical load of 125N to minimise lag screw wear. Testing was completed at 0° static flexion and 20°, 30° and 40° dynamic flexion. A series of tests were also completed on a 135° DHS with a 70mm lag screw length at the same application rates, at 0° static flexion and 40° dynamic flexion only.

Results

The results for the Gamma Nail indicated that an increased rate of loading reduced the forces required to initiate sliding. However the faster application rates also reduced the effect of the dynamic flexion angles on the sliding force. The quasi-static rate of application of the axial load resulted in the highest sliding forces within all four loading conditions (Fig 5.13). The reduction between quasi-static loading and "fast" loading under 0° static flexion was around 25%, equivalent to the reduction between 40° dynamic flexion and 0° static flexion under quasi-static loading (Appendix A: Table 25). As the dynamic angle of flexion increased, the reduction in sliding force due to the application rate decreased.

The results implied that an optimum condition existed between the angle through which the hip joint was flexed and the rate at which load was transmitted through the joint, ie. when the application rate was maximum, under increased angles of dynamic flexion. Limitations with the current test rig made it impossible to synchronise the application of load with the flexion-extension cycle as would occur in normal gait, however these results clearly demonstrated the significance of loading rate and flexion-extension cycles on sliding forces. The three rates employed in the application rate test sequence were all relatively slow in comparison to those associated with normal daily living activities.

The DHS exhibited exactly the same trend of results as the Gamma Nail, with a 14% reduction between the two extreme loading rates at 0° static flexion and a 16% reduction between 40° dynamic flexion and 0° static flexion under quasi-static loading (Appendix A: Table 26). The optimum sliding condition was therefore not dictated by lag screw geometry alone.

5.3.4 Comparative Tests

A complete test sequence was undertaken to compare the overall performance of the Gamma Nail and the DHS, under a range of comparative conditions.

i) The two implants were compared with equivalent bending moments. *In vivo* the lateral or medial positioning of the two implants would not significantly alter the lag screw length protruding from the barrel, due to the different length of the barrels themselves.

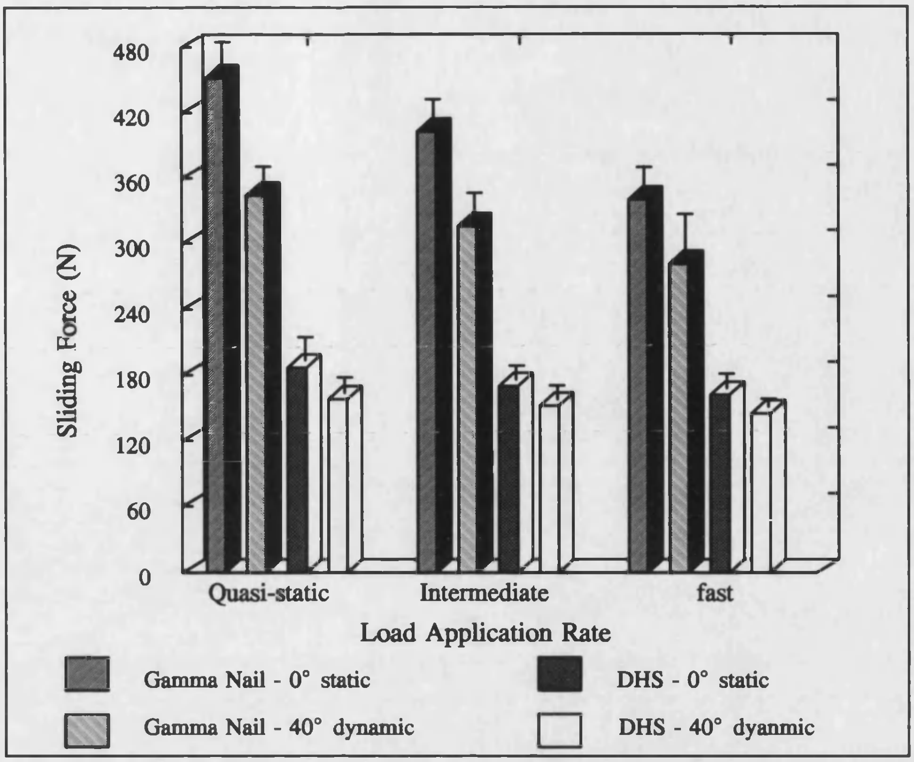

Fig 5.13 - The effect of load application rate on the mean sliding force, for the two implants at two flexion conditions, from 72 tests.

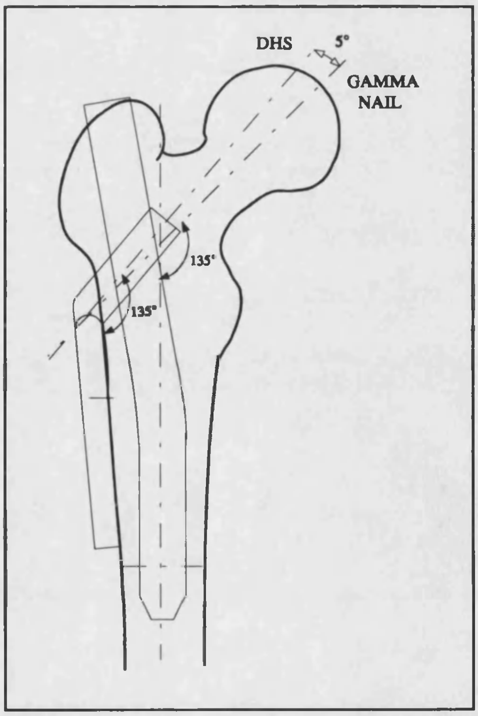

Fig 5.14 - The relative implant angles are shown to be 5° different due to the anatomic femoral angle.

The implant angles themselves predetermine the relative length of the lag screws, the higher angles requiring longer screw lengths to be correctly positioned within the femoral head.

ii) Due to the angle between the femoral axis and the external surface of the bone, it was considered appropriate to compare the 140° Gamma Nail directly with the 135° DHS. The intramedullary positioning of the Gamma Nail is complemented by an approximate 5° angle of the femoral wall onto which the DHS plate is screwed. This results in the 140° Gamma Nail and the 135° DHS being aligned along the femoral neck shaft (Fig 5.14).

Method

To equate the bending moments for the two implants, using the static vertical loads outlined by Kyle *et al.* (1980) for the relative nail/plate angles, the lag screw lengths tested were altered to achieve an equal bending moment of 13.3Nm at the barrel. Under these conditions a set of static and dynamic flexion tests at 0°, 20°, 30° and 40° results were completed on both implants

Gamma Nail:	$\beta = 140°$,	$L_n = 86.5$mm,	$B_0 = 154$N
DHS:	$\beta = 135°$,	$L_n = 70.0$mm,	$B_0 = 190$N

Results

For the Gamma Nail the dynamic result indicated a 40% reduction in sliding force between 0° static and 40° dynamic flexion. The static result was much less at approximately 14% (Fig 5.15). This supports the previous relationship for sliding under dynamic conditions. The recorded sliding forces for the 0° static flexion condition were 7% higher in the static flexion series than the dynamic flexion. The surface damage was more severe due to sliding under static flexion conditions as the sliding surface remained constant, resulting in higher static friction (Appendix A: Table 27 & Table 28).

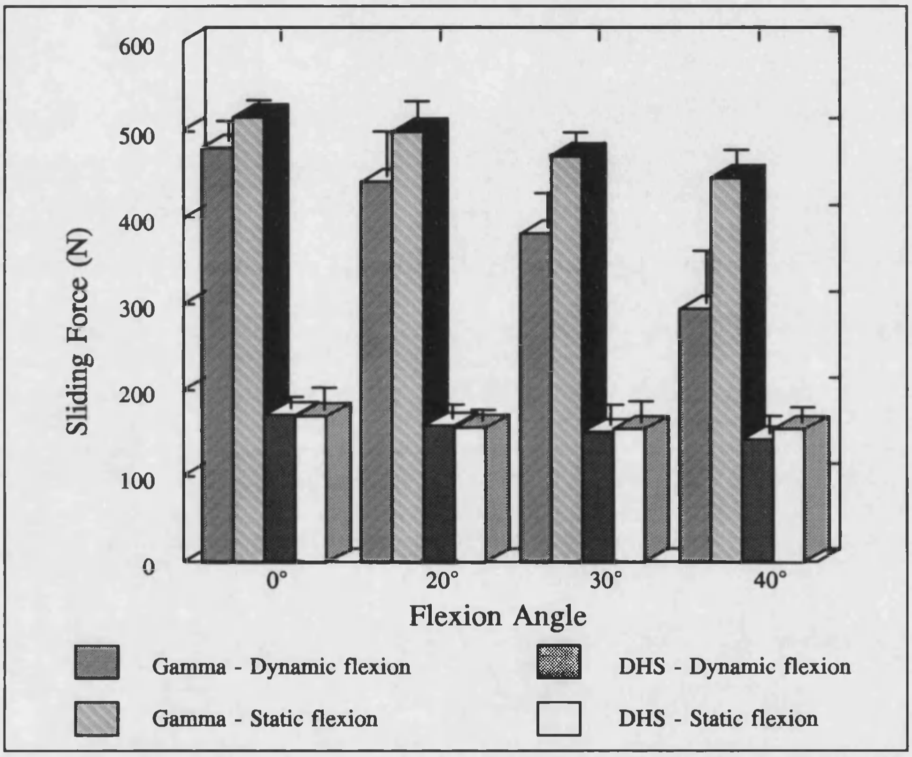

Fig 5.15 - The sliding forces for the Gamma Nail and DHS under comparable bending moments at two flexion conditions, from 96 tests.

The DHS behaved in a similar manner to the Gamma Nail under both loading conditions. The reduction between 0° static and 40° dynamic flexion was less than the Gamma Nail results, at around 17%. Under the static flexion conditions the decrease was around 9% between 0° and 40°. The overall sliding forces required by the DHS were significantly less than those for the Gamma Nail. However, with the reduced sliding force of the Gamma Nail under dynamic flexion, the ratio of sliding forces between the two implants was again reduced to approximately 2:1, whereas for the static conditions this figure was much higher at 3:1.

5.3.5 Lubrication

The exact conditions into which a sliding hip screw is implanted are not known. The lubricating medium within the femur could be blood or fats or a combination of many biological fluids. No previous studies have looked at the performance of the implants under physiological conditions. As a results of this, no guidelines were available for the lubricating medium. Test sequences were undertaken on the Gamma Nail using water and lipid under different conditions in an attempt to simulate *in vivo* conditions more accurately.

Method

A series of tests were undertaken dripping water onto the lag screw as the lubricant. Tests were completed at 0° static flexion and 20°, 30° and 40° dynamic flexion. The water was then replaced by lipid which was dripped onto the screw for a comparative dynamic flexion test series and a second static flexion series. The final test series enveloped the sliding surface within the lipid lubricant and a series of dynamic flexion tests were undertaken. The basic test sequence employed a 135° implant angle with the calculated 190N static vertical load and a 100mm lag screw length.

Results

The initial test series using water as the lubricant caused the accelerated breakdown of the sliding surface of the lag screw (Fig 5.17). Water was thus not considered an appropriate medium and its use was discontinued (Appendix A: Table 29).

For the tests with the lipid dripped onto the sliding surface of the lag screw, the reduction in sliding force between 0° static flexion and 40° dynamic flexion was around 16%. In the static flexion tests the lubricant did not alter the pattern of sliding force reduction found with the previous unlubricated results, a reduction of around 6% being recorded (Fig 5.16). With the lubrication system replaced by a 'bag' of lipid around the implant, the expected effect on the axial sliding force by the dynamic flexion was again reduced. The decrease between 0° static flexion and 40° dynamic flexion being around 10%, performing in a similar manner to the static flexion tests (Appendix A: Table 30 & Table 31). The use of lipid as a lubricant, to simulate the physiological conditions of the Gamma Nail, appeared to result in a change in the characteristics of the sliding device.

By totally enclosing the lag screw and nail junction, the load bearing surfaces were cushioned by the lipid and the expected drop in the sliding force due to a variation in the sliding surface, was not apparent. The lubricant was therefore forming a 'buffer' between the two surfaces which were no longer in direct contact. There was minimal surface wear of the sliding surface under this condition. In the dry state the point of initiation of sliding was easily detectable on the recorded results. However, in the lubricated state this point was less defined and the movement more gradual. This gradual movement made the point of initiation of sliding difficult to detect. The precise conditions experienced by the implant *in vivo* are not known and the degree of lubrication not fully understood.

The lag screws fully enclosed within the lipid did not show any significant evidence of wear after sliding. From discussion with orthopaedic surgeons (Fogg (1996)), the surface of a lag screw, after explanting from a patient, shows signs of wear due to sliding. This suggests that the lubrication represented by the fully enclosed test condition did not represent the clinical situation. The dry testing undertaken throughout the study was relatively simple. The introduction of a dripped fatty lubricant onto the surface of the lag screw makes the test protocol significantly more complex and unrepeatable. It could therefore be argued that the dry unlubricated testing is an adequate representation of the loading conditions.

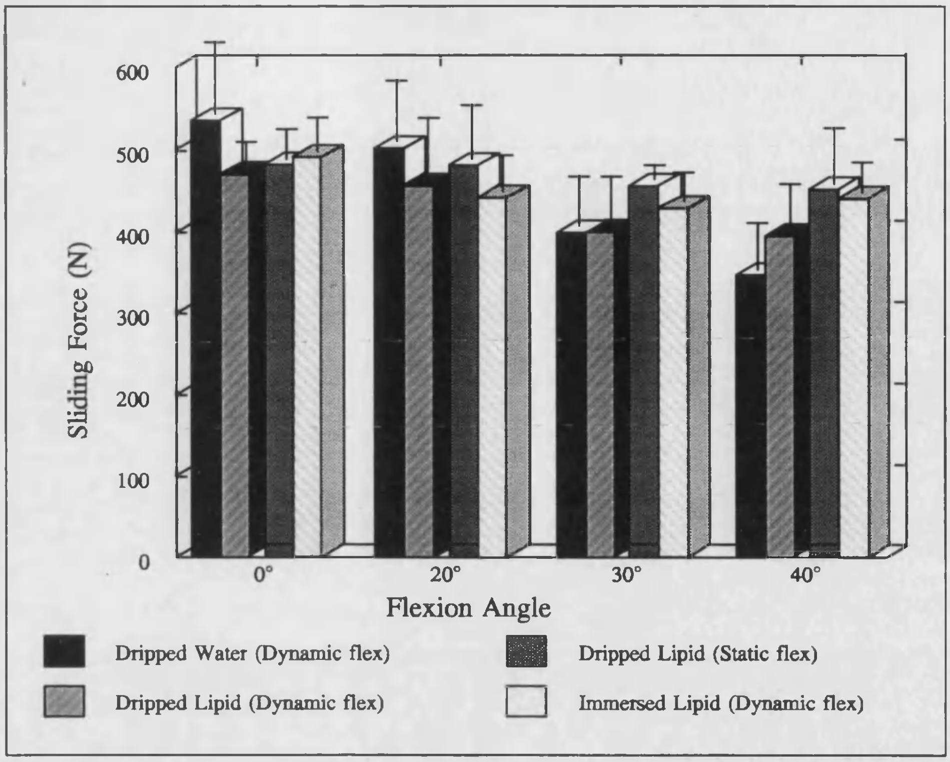

Fig 5.16 - The effects of lubrication on the mean sliding forces for the Gamma Nail, from 92 tests.

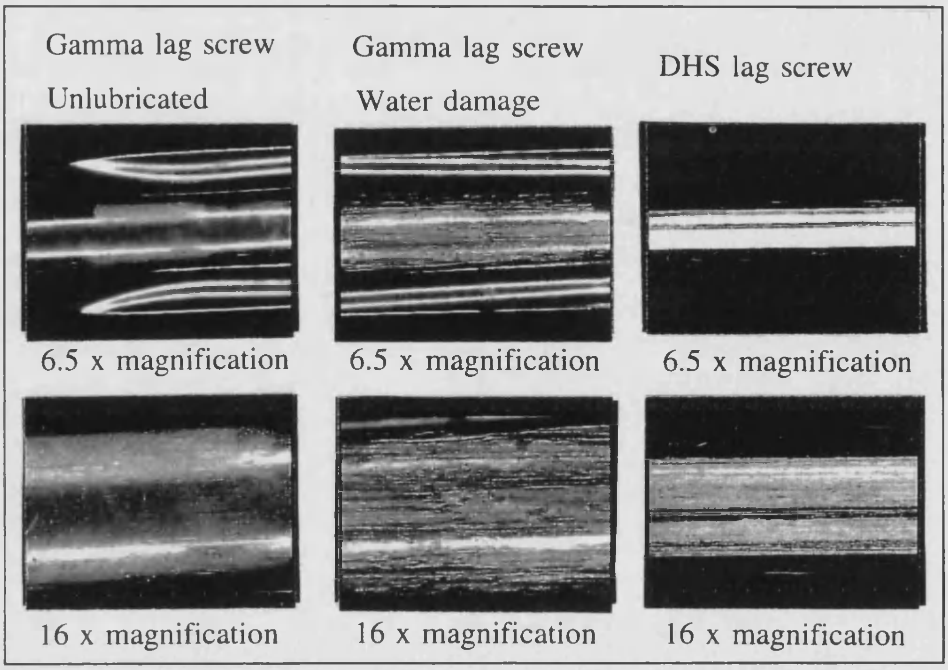

Fig 5.17 - Magnified photographs showing the wear along the sliding surface of the lag screws.

5.3.6 Surface Tests

The surfaces of the lag screws used within the study were examined under an optical microscope for damage due to sliding within the barrel (Fig 5.17). The worst wear damage appeared on the lag screws used within the lubrication tests where water had been employed as the lubricant. The unlubricated metal surface would have been coated in a layer of oxidised material which would provide protection against wear damage. When the metal is unable to replace this oxidised layer, the unprotected surface would therefore became damaged more rapidly.

A Rockwell hardness test and a surface roughness test (Talisurf) were undertaken on the two different types of lag screw prior to testing, with no significant difference being identified. The Gamma Nail had a mean hardness (HV_{300g}) of 375 compared to 330 for the DHS. From the surface roughness test, the Gamma Nail had a mean R_a value of 0.113 μm. The DHS had a mean R_a value of 0.11 μm on the curved sliding surface, increasing to 0.32 μm on the flat surfaces. Each test was completed on three individual lag screws with six test completed on each one.

A single static flexion sliding sequence was completed on a 135° Gamma Nail and a 135° DHS lag screw and the damage visually examined after the one test. The DHS exhibited more surface damage than the Gamma Nail, despite the reduced reaction forces at the barrel creating less surface friction.

5.3.7 Repeatability of Testing Procedure

Method

To establish the repeatability of the test method itself, a series of tests were completed on the Gamma Nail, completely removing the implant and resetting the test rig between each individual test performed. A 135° nail angle was used with a 105mm lag screw length at 0° static and 30° dynamic flexion. Six complete test sequences were performed at each flexion angle, each test sequence consisting of six individual tests.

Results

The standard deviations identified within each test sequence were within an acceptable range (Appendix A: Table 32). The results for the static tests appeared to be more consistent than the dynamic results, with a coefficient of variation of 13.31% compared to 19.33%. The results support the test protocol used throughout this biomechanical study.

5.4 Discussion

The problem of screw jamming due to the mechanical behaviour of the implant is a significant factor in the performance of sliding hip screws. This chapter examined the problem from the position of screw sliding and the optimum conditions required for this to take place.

The initial test sequences examined the individual parameters that could effect the sliding performance of the lag screw. From simple force resolutions the axial force required for the lag screw to slide (F_s) was established to be a function of the length of the lag screw protruding from the barrel (L_n), the perpendicular load at the end of the barrel, known as the vertical component of bodyweight (B_0), and the length of the lag screw within the barrel of the implant (L_b).

$$F_s = \mu_0 B_0 (1 + L_n / L_b)$$

Increased lag screw lengths protruding from the barrel of the nail or plate were found to require greater forces to initiate sliding (section 5.3.1.1), supporting the above equation. The screw length *in vivo* is determined by the femoral neck geometry of the patient. The distance of the screw tip from the cortical bone layer of the femoral head is reported in the literature to be 10mm optimal distance. The only surgical variable in the lag screw length could be due to the implant angle itself, but this in turn is determined by the fracture configuration and the anatomical angle of the femoral head and neck.

The static vertical load used throughout the testing represented the vertical component of bodyweight of the patient, the maximum value calculated from the equation:

$$B_0 = P\sin\,(159°\text{-}\beta)$$

It was shown that the greater the value of B_0, the greater the sliding force required to overcome it (section 5.3.1.2). The third parameter of barrel length was shown with the DHS (section 5.3.1.3), where a reduction in barrel length for a constant implant angle (ß) resulted in an increase in the axial sliding force. Both these results support the equation for axial sliding force.

The screw length both within (L_b) and protruding from the barrel (L_n) determined the reaction forces and bending moment experienced by the implant due to the vertical component of bodyweight (sections 5.3.3.1 & 5.3.3.2). With equivalent reaction forces the two implants required comparable sliding forces under static conditions of flexion. Under equivalent bending conditions the Gamma Nail required an axial force 50% greater than the DHS, where the reaction forces at the barrel of the Gamma Nail were over 50% greater than for the DHS, due to the reduced barrel length.

At the point of exit from the barrel $\quad R_1 = B_0(1 + L_n/L_b)$

and $\quad M = B_0L_n$

Therefore the barrel length and more importantly the length of lag screw within the barrel is a significant parameter on the forces required for sliding. These results also suggest that an important clinical factor when selecting the implant is to ensure the length of lag screw itself is sufficiently long to be fully engaged in the barrel when positioned in the femoral head. A reduction in the length of screw within the barrel will be detrimental to the sliding performance.

All the preceding results have supported the equation for the axial sliding force under conditions of static flexion ie. no rotational movement of the implant. However, from the results for equivalent reaction forces, under conditions of dynamic flexion it can be seen that the relationship between the sliding force and the reaction force is significantly altered. The sliding force for the both implants is reduced although none of the other parameters have been altered, particularly with the Gamma Nail where this reduction is around 50% under conditions of 40° dynamic flexion. This implied that there are other influences on the sliding characteristics.

As outlined in section 2.1.3, the *in vivo* forces at the hip have been shown to be 2.7 times body weight for a single leg stance. Hip forces during walking vary depending on the speed, but have been recorded between 3 and 7 times bodyweight. This is significantly reduced post-operatively by assisted walking, such as using crutches, which can reduce the load to 1 times bodyweight. Savvidis *et al.* (1989) suggested that even during the swing phase of normal walking 0.85 times bodyweight is experienced through the hip and Bergmann *et al* (1990) recorded forces as high as 0.4 and 1.5 times bodyweight respectively from simply abducting and lifting a leg in bed. From an everyday movement such as rising from a chair unassisted, when the hip is at maximum flexion, forces of nearly 6 times bodyweight have been recorded (Rodosky *et al.* (1989)).

To establish whether the forces attained in these test sequences are theoretically possible *in vivo*, the results can be expressed in terms of multiples of bodyweight:

It has been shown that $B_0 = P\sin(159°-ß)$

and thus the available axial force is $A_0 = P\cos(159°-ß)$

$A_0 = B_0/\tan(159°-ß)$

(The implant will slide if $A_0 > F_s$)

For current test sequences $P = \text{bodyweight (N)}*2.7/4$

multiple of bodyweight $B_m = 2.7\ F_s/A_0$

$= 2.7\ F_s\tan(159°-ß)/B_0$

Considering the equivalent reaction tests in terms of multiples of bodyweight (Appendix A: Table 33), the DHS would appear to slide under both the static and dynamic conditions with a maximum of 1.45. The forces required for the Gamma Nail to slide could only be achieved under dynamic conditions, with values of 4.26 at 0° static reducing to 2.12 at 40° dynamic flexion.

The dynamic flexion of the test rig has thus been shown to significantly reduce the forces required by the implants to initiate sliding (section 5.3.3.1). The greater the degree of flexion, the larger the reduction in sliding force. This suggests that sliding of the implant is induced by movement of the patient, and that any biomechanical tests performed under static conditions do not sufficiently represent the clinical situation. Increased static angles of flexion also reduced the sliding forces, the Gamma Nail lag screw design resulting in improved sliding surfaces at constant angles of flexion. Calculating the multiples of bodyweight required by the two implants in the comparative static and dynamic flexion test (Appendix A: Table 34 & Table 35) the same trend is again exhibited, with the DHS bodyweights attainable under all flexion conditions and the Gamma Nail under increased dynamic flexion.

The rate of loading of the implant also affected the required sliding force. Unfortunately, the initial test rig was not able to synchronise dynamic movement cycles with the loading, to evaluate individual movements. However the reduction in sliding force created by flexion angles in both the static and dynamic conditions linked to the rate of load application, suggest that sliding could occur under a number of conditions ranging from slow rising from a chair to relatively rapid walking for both implants. The introduction of a lubricating medium into the test protocol lead to unreliable results due to the difficulty in detecting the point of initiation of sliding. The precise lubrication condition of the implants within the cortical bone of the femoral head and neck is not known. It was felt that the introduction of lubrication into the test procedure did not enhance the understanding of the overall performance of the devices.

5.5 Closure

This study indicated that biomechanical static testing of sliding hip screws does not accurately represent the loading conditions *in vivo* and would lead to inaccurate and unrealistic results. Both loading rates and dynamic flexion cycles alter the loading pattern of the lag screw and significantly reduce the loads to initiate sliding of the lag screw. From this study it was not possible to evaluate realistic dynamic loading cycles, as limitations in the test rig prevented synchronisation of the load application with the flexion cycle.

Chapter 6

PROSPECTIVE RANDOMISED CLINICAL TRIAL

In order to establish the overall performance of the Gamma Nail and DHS in a sample patient group, a clinical trial was required. The purpose of this trial would be to collate results which would assist in the understanding of the overall performance of sliding hip screw devices and highlight the conditions under which they must be tested in laboratory studies to realistically represent the clinical situation.

A prospective, comparative, randomised multicentre clinical trial (Laupacis *et al.* (1989) and Raven (1991)) was undertaken. All the patients entered into the study would have had their trochanteric femoral fractures internally fixed with a Gamma Nail or a DHS. This would establish whether there was any significant difference between the outcomes of the treatments. The trial was designed by the author in conjunction with Lindsey Hallam (Trial Manager, Howmedica International). In addition to the standard clinical data derived from a clinical trial, information would be gathered to focus on the biomechanical performance of the implants.

All the patients would be followed-up post-operatively to assess both the clinical and biomechanical performance of the implants. Follow-up assessment was to be completed by the author at special outpatient clinics within the orthopaedic department of Princess Margaret Hospital, Swindon. The results from only one surgical centre would be outlined as a sample group, with no statistical analysis. This sample group would represent the population of the on going clinical trial.

6.1 Trial Protocol

A total of approximately 50 patients were entered into the study, recruited from Princess Margaret Hospital, Swindon. To evaluate the overall implant performance three specific areas of interest were investigated:

i) Operative procedure
ii) Patient recovery
iii) Biomechanical implant performance

The study centre involved in the trial had previously used the DHS as the treatment of choice for internal fixation. To overcome the obvious problem of familiarity with the DHS by the participating surgeons, the orthopaedic surgical centre received the new Gamma Nail implants and accompanying surgical equipment trays prior to the start date for the trial. A representative from Howmedica instructed the surgical teams in the protocol for the implant and was present for initial operations, where requested. A minimum of 5 Gamma Nails were then inserted by each surgeon before any cases were included in the trial.

Certain criteria had to be set prior to initiation of the trial to maintain a level of consistency between the different surgical teams and orthopaedic care nurses. These included the qualification of patients to be in the trial data set, the type of data collected, by whom and when, the operative procedure used and the immediate post-operative treatment (section 6.1.1 - 6.1.4).

6.1.1 Patient inclusion

The trial included all patients under the care of the participating investigators who required internal fixation for a peritrochanteric or high subtrochanteric fracture and who, in the opinion of the investigator, were suitable to receive a sliding hip screw device. The patients were also required to meet the following inclusion criterion:

1) Patients who were capable of and had given informed consent or a relatives consent, to their participation in the study.
2) Patients who were capable of and willing to follow their surgeons directions and comply with the post-operative follow-up.

The following patients were excluded from the study:

1) Patients who had previously fractured the same femur, where the fracture had

not yet consolidated.

These criteria were approved by the Ethics committee at Princess Margaret Hospital prior to initiation of the trial.

6.1.2 Data Collection

Four individual case record forms (Appendix E) were designed, adapted from standard trial protocols. These forms would contain the complete set of patient information required for the trial, recorded separately from the standard medical history file maintained by the hospital. For each patient, 100 different pieces of information were entered into the case record form. The four individual forms collected data at different stages in the medical history, the data collected by different personnel on each form.

The first form was a registration form, on which trial reference numbers were allocated to the patient and basic information recorded about the fracture and the randomised treatment. The form was filled in by the ward registrar or senior house officer (SHO) when the patient was admitted to the ward, prior to treatment.

The second form included all the details of the patients hospitalisation and could be broken down into three sections. A pre-operative assessment of the patients conditions and pre-admission details was recorded by the registrar or SHO. The per-operative details of the treatment used and the operation were recorded by the operative surgeon along with the immediate post-operative details of the implant position. The final section was completed by the nursing staff or physiotherapist, recording the patients ability and complications prior to discharge.

The remaining two forms were completed at post-operative follow up, in the outpatient clinics, by the author. They recorded an assessment of the patients ability and the implant performance and position, at three months post-operative and six months postoperative.

The additions included in these forms, compared to a standard clinical form, consisted of information regarding the precise positions of the lag screw within the femoral head pre- and post-operatively, including the lag screw length protruding from the barrel and the distance of the tip of the screw form the cortical bone. In relation to this the ability of the patient was regarded closely, recording the walking gait and estimated walking speed, the assistance required when walking and the weight of the patient.

6.1.3 Surgical Procedure

The surgical procedure employed for the insertion of the two implants was that recommended by the implant manufacturers using the relevant instrumentation and techniques. The lag screws for both implants were placed centrally within the femoral head, at a distance of approximately 10mm from the cortical bone at the head of the femur, as recommended in the literature and throughout the cadaveric study. No hammering was employed in the insertion of the Gamma Nail and the use of distal locking screws was optional.

6.1.4 Post-operative Mobilisation

All patients were mobilised as quickly as possible following operative treatment. In cases where the Gamma Locking Nail was used it was recommended that the patient was mobilised on the first day post-operative. In patients where the Dynamic Hip Screw was used mobilisation and weight bearing was recommended as tolerated by the type of fracture. The progress from non-weight bearing to weight bearing was recorded by the nursing staff.

6.2 Patient Record Forms

Patients were assessed according to the patient record forms, pre-operatively, per-operatively and post-operatively (Appendix E). Standard anteroposterior and lateral radiographs were taken on admission, in the immediate post-operative period, at discharge and at the subsequent post-operative follow-ups in the clinics. In order to maintain patient confidentiality the patient's name or address was not recorded on the form. However, for means of tracing the patient if necessary, the patients hospital number was recorded. Information to be recorded on the form by the registrar or SHO was indicated by A or B, by the operating surgeon by a C, by the nursing staff by a D and by the author by and E, to avoid confusion.

6.2.1 Pre-operative Assessment

Information was recorded by the Registrar or SHO and the operating surgeon.

A1 Dates of Birth, accident, admission, and operation (registration form),

B1 Activity level, mental ability and residence prior to admission,

B2 Any co-existent disease or concomitant therapy,

B2 Any anti-coagulant or antibiotic prophylaxis and additional therapy,

C1 Classification of fracture using the Evans and Gustilo system.

6.2.2 Per-operative Assessment

Information was recorded by the operating surgeon.

C2 Type of anaesthesia,

C2 Reduction of fracture performed,

C2 Details of the implant used,

C2 Estimated blood loss and blood given,

C2 Length of the operation and any complications or difficulties,

C3 Position of the lag screw within the femoral head and extending from the barrel.

6.2.3 Post-operative Assessment

Post-operative assessment at discharge was recorded by the operating surgeon and nursing staff.

D1 Any clinical or mechanical complications,

C4 Position of the lag screw,

D1 Dates of mobilisation and the hip function,

D1 Type of residence discharged to and date of discharge.

Subsequent post-operative follow-ups at 3 months and 6 months was recorded by the author.

E2 Activity level, mental test score and current residence,

E3 Any clinical or mechanical problems,

E3 Position of the lag screw,

E3 Dates of mobilisation and hip function,

E3 Fracture consolidation and any removal of device.

6.3 Results

From the 50 cases included in the trial from Swindon, 31 were treated with DHS and 19 with Gamma Nails. The possible drop in the expected number of Gamma Nail patients was due to the unfamiliarity of the surgeons with the treatment. This resulted in a temptation to omit the patient from the trial if a Gamma Nail was drawn as the treatment, from the randomisation cards.

Of the 31 DHS cases, 10 were stable fracture configurations and the remaining 21 were classified as unstable. For the Gamma Nail there were 4 stable fractures, 13 unstable fractures and 2 high subtrochanteric fractures, both inherently unstable (Appendix A: Table 36). Of the 50 fractures treated, 9 cases died within 6 months of follow up (1 Stable Gamma Nail, 2 stable DHS and 6 unstable DHS). One of the DHS cases died 5 hours post-operative due to heart failure, the remaining deaths could not be directly related to the operative procedure.

A breakdown of the entire sample population revealed that there were 36 females and 14 males, an unusually high proportion of males compared to other clinically reported sample groups. The average age of the patients was approximately 80 years old. The mental ability of the implant patients groups was 8.7 for the Gamma Nail and 7.1 for the DHS. This was determined from a simple mental assessment consisting of 10 standard questions (Appendix E). However, if the cases of patients deaths were excluded form this mental score, there was an increase in the mental ability of both groups to around 9. The mental ability of the deceased patients was 3 and 1.7 respectively. Mental ability itself has been reported to be a significant factor in the outcome of operative treatment (Parker *et al.* (1993)), a finding supported in these results (Appendix A: Table 37).

From a purely clinical perspective, the average time to perform the two operative treatments was greater for the Gamma Nail than the DHS, 84 minutes compared to 68 minutes. Considering the two implants in the stable and unstable fracture groups, the DHS consistently took around 20 minutes less than the Gamma Nail. This would be a significant parameter in the eyes of any surgical team. However, in terms of blood loss during the operation, the average loss for the Gamma Nail was 333 mls whereas the DHS had an average loss of 430 mls, both implants performing worse in the cases of the unstable fractures. This blood loss was a result of the incision required by the two implants, the smaller incision for the intramedullary nail causing less blood loss despite the longer operative procedure (Appendix A: Table 38).

One factor in assessing the viability of a treatment is the duration of stay in hospital for the individual patients. From the recorded data, the average recorded length of stay for the Gamma Nail was approximately 19 days, compared to 18 days for the DHS. A further classification is the time the patients spends bed bound post-operatively, prior to weight bearing. For the elderly patient group, the sooner they are out of bed, the better the long term prognosis for the treatment. The Gamma Nail is a more stable implant immediately post-operative, able to support more of the total joint forces. The patients in this group were weight bearing an average of 1.6 days post-operative, compared to 3.8 days for the DHS (Appendix A: Table 39).

The success of any treatment can be assessed in terms of the return of the patient to their pre-operative condition. Two estimates of this were the mobility of the patients pre- and post-operatively and the long term housing, in terms of living at home and being relatively independent or being in some form of institution. For the Gamma Nail, 60% of the cases were walking without any form of aid pre-operatively, a figure which dropped to 6% post-operatively, with 17% of cases completely bed/chair bound 6 months postoperative. For the DHS 48% of cases were walking unaided pre-operative, reducing to 4% post-operatively, once again with 17% unable to walk at all 6 months post-operative. In terms of housing, 78% of the Gamma patient group lived in their own homes pre-operatively, of which only 61% of the patient group returned.

With the DHS group these figures were 70% reducing to 64%. Both groups therefore appeared to be comparable under these parameters (Appendix A: Table 40).

Mechanical success or failure of an intertrochanteric hip fracture can simply be determined by failure or non failure of the implant treatment. With the Gamma Nail there were 3 failures, 2 cut-out failures and one unusual failure of the implant itself around the barrel, with a subtrochanteric fracture. The fracture in this case had not united at 6 months post-operative and the full joint loading was being borne through the implant, leading to fatigue. With the DHS there were 3 cases of lag screw cut-out. Of all these potential failures, two reoperations were required with the Gamma Nail, but none with the DHS.

The lag screw placement for the two implants was generally very good, the average (mode) positions for the lag screw within the femoral heads being central (position 5) for both. The distance of the tip of the lag screw form the cortical bone layer was on average 9.9mm for the Gamma Nail and 8.5mm for the DHS. Considering the two cut-out cases with the Gamma Nail, both of them could be attributed to poor lag screw placement within the femoral head, one being positioned central and superior (position 2) with the lag screw 5mm from the cortical bone (requiring reoperation) and the other superior and posterior (position 3), both considered high risk areas. With the three DHS cut-out failures all from unstable fracture configurations, the lag screws were positioned central and superior (position 2) in all cases. The lag screw tip was positioned at a sufficient distance from the cortical bone layer to minimise damage in these particular cases, with an average distance of 14mm. Once again these failures could be attributed to poor positioning of the lag screw.

Mechanical success or failure of the two implants could be assessed in terms of sliding of the lag screw within the barrel. From the lag screw length extending from the barrel measured from the per-operative X-rays, and the length record at the post-operative follow-ups, any sliding of the lag screw within the barrel could be detected. For the failures due to lag screw cut-out, no reduction in lag screw length extending from the barrel was measured in any of the cases. From this it was assumed that the lag screw had jammed within the barrel.

A sample was taken from the trial population, including lag screws that had jammed and those that had moved within the barrel, for both implant groups (Appendix A: Table 41). Two jammed, cut-out implants were included from both groups along with four 'successful' implants. The range of ability of movement for both groups was matched, ranging from bed/chair bound and only able to move with human assistance, to unaided walking post-operatively. For each of these cases, the body weight and lag screw length protruding from the barrel was established from the trial data. For the successful Gamma Nails the average body weight was 66kg, and for the successful DHS's the average body weight was 60kg. The average body weight for the two implants for the cut-out cases was 58kg and 55kg respectively. The average lag screw lengths for the same four categories was 72mm and 44mm for the two successful groups and 63mm and 59mm for the cut-out groups. All the sample population used 135° implant angles.

6.4 Discussion of Biomechanical Results

For the patient sample taken from the trial group, the maximum vertical component of bodyweight experienced by the lag screw could be calculated.

From section 5.4

$$B_0 = B'weight * 9.81 * B_m \sin(159° - ß)/4$$

Where B'weight = Body weight

B_m = multiple of B'weight

It was assumed that for the different walking abilities, a different maximum value of P was possible ($P = B'weight * B_m/4$).

Human assistance	$B_m = 1$
2 canes	$B_m = 1.6$
1 cane	$B_m = 1.9$
Normal slow walk	$B_m = 3$

From the assumed multiples of bodyweight experienced by each lag screw the respective available axial force could also be calculated.

$$A_0 = B'weight * 9.81 * B_m \sin(159°-ß)/4$$

In section 5.4 it was stated that the available axial component of force must exceed the force required by the lag screw to initiate sliding before sliding would occur ($A_0 > F_s$). From the Gamma Nail sample group where sliding occurred, the available axial force ranged from 41N to 266N and for the DHS this range was 59N to 179N (Appendix A: Table 42). For the jammed lag screws the maximum available axial force for the Gamma Nail and DHS was 81N and 91N respectively.

From the results obtained in chapter 5, the axial sliding forces (F_s) required by the Gamma Nail lag screw were considerably higher than the available axial forces (A_0) calculated from this clinical data. Under 0° static loading conditions the axial sliding force was over 500N, with a reduction of around 40% under 40° dynamic flexion conditions (section 5.3.1.2). With the DHS under 0° static flexion, loads of over 300N were recorded.

Sliding of the lag screw was recorded in the clinical trial in the majority of the cases. For the small sample group taken from the patients included in the trial, the available axial loads, calculated from the patients bodyweight and mobility levels, would not have resulted in sliding under any of the biomechanical conditions represented on the dynamic flexion test rig. The reduction in axial sliding force required by both implants under dynamic flexion conditions, reported in the biomechanical study, approached the available axial forces seen in this study. Due to the lack of synchronisation of the loading and movement parameters on the test rig, more realistic loading conditions could not be represented.

6.5 Closure

The clinical results clearly show that sliding of the lag screw occurs in the majority of patients, ranging from small ladies who are unable to walk without human assistance to heavier patients who walk unaided. However, the biomechanical sliding forces derived from the dynamic flexion test rig, suggested that sliding would only occur in a few cases, even with the DHS. These cases would all be under dynamic flexion conditions, with a relatively large bodyweight.

Despite the obvious discrepancies with the biomechanical results, no published studies under static loading have achieved results as realistic as these. Dynamic flexion is therefore the most suitable test protocol when investigating sliding hip screws. The assumption was therefore made that sliding of the lag screw *in vivo* could occur under conditions of flexion not represented in the biomechanical analysis. High flexion movements such as chair rising or movement in bed could produce a sufficient force to induce sliding, as an alternative to the walking cycles investigated. A more realistic representation of physiological movement cycles would be required to investigate these conditions.

Chapter 7

BIOMECHANICAL SYNCHRONISED LOADING STUDY

From the clinical data obtained in chapter 6 it was concluded that sliding of the lag screw would rarely occur under walking conditions. From a simple biomechanical analysis of the trial data, the *in vivo* axial implant forces were calculated for individual patients, in a range of cases where sliding and jamming had occurred. The mobility of the patients was recorded to estimate the maximum loading cycles due to walking that would be experienced by the implant.

The previous biomechanical study (chapter 5) investigated the forces required to initiate sliding of the lag screw under static and dynamic flexion cycles with increased rates of load application. No previous studies in the literature had examined the sliding forces under conditions of dynamic flexion. However, even under conditions of maximum dynamic flexion with an increased loading rate, the results suggested that sliding of the lag screw would occur in only the minority of clinical cases. The sliding forces required by the implants was consistently greater than the axial implant forces calculated from the clinical data where sliding had occurred.

Further biomechanical analysis of the Gamma Nail and DHS was therefore required and a synchronised loading rig was designed and built for this purpose. This would allow more realistic loading conditions to be presented, recreating the *in vivo* sliding conditions of the lag screw in the laboratory environment.

7.1 Test Rig Design

Synchronised Loading Test Rig

A test rig was developed using the basic design of the earlier dynamic loading test rig (Fig 7.1).

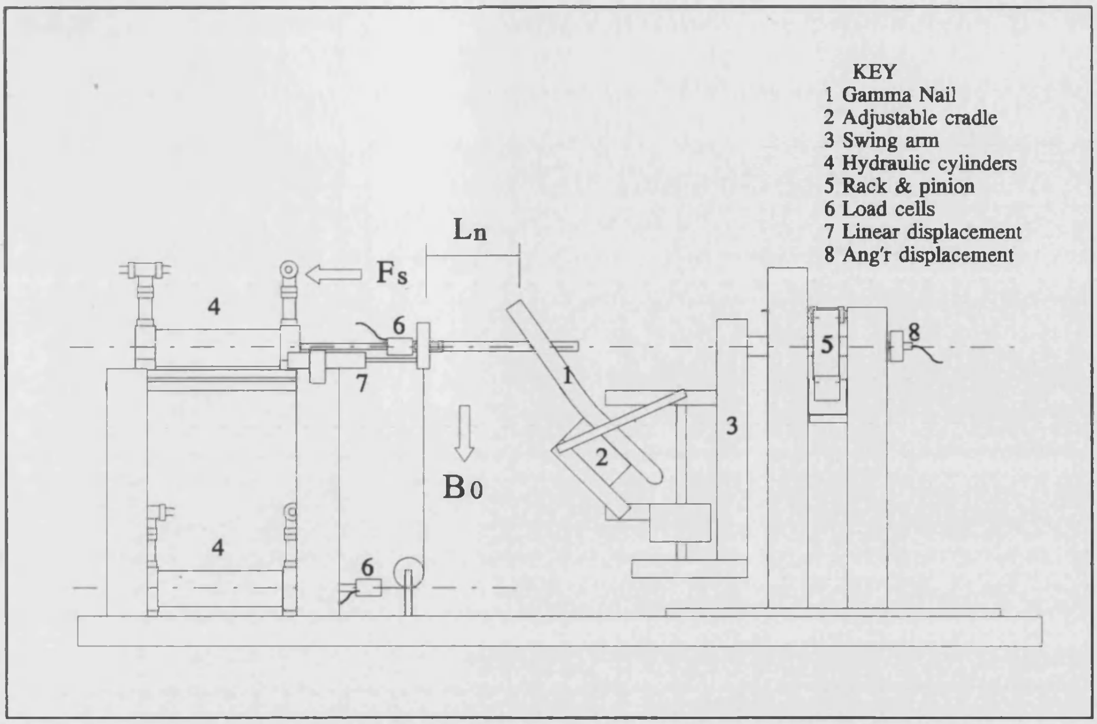

Fig 7.1 - Synchronised loading test rig

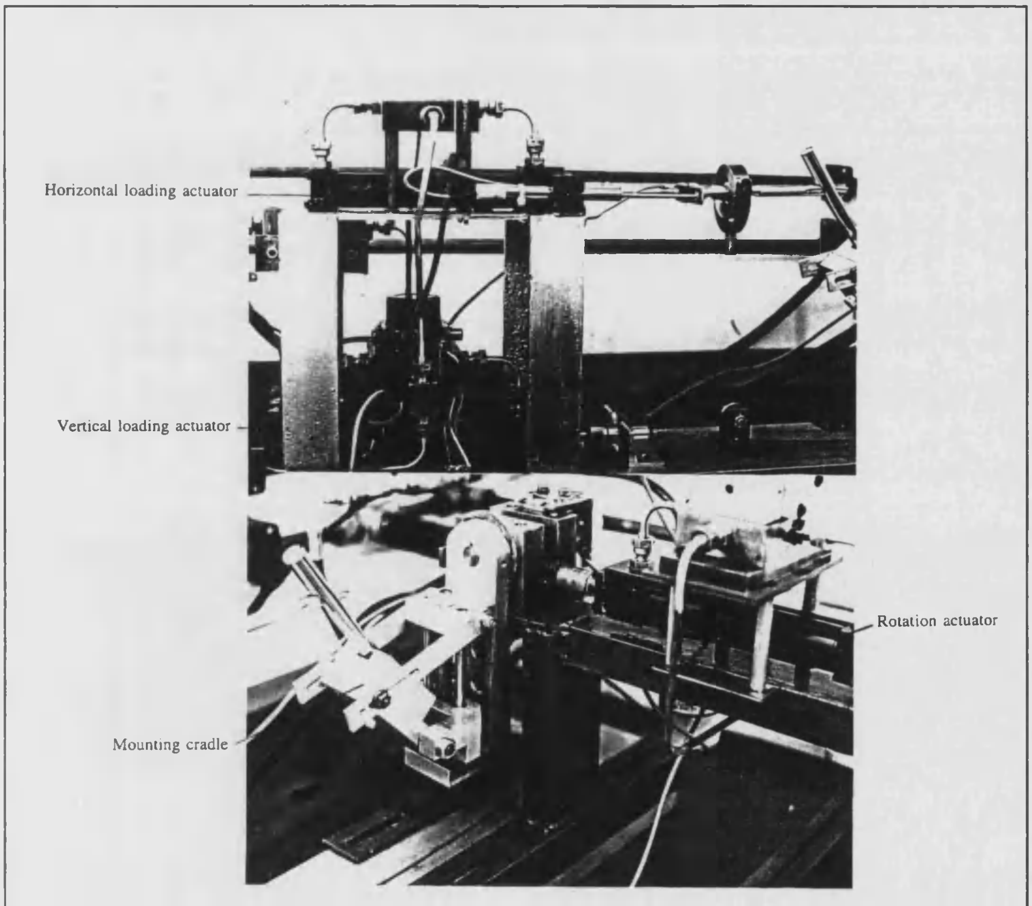

Fig 7.2 - Photographs showing the loading (top) and flexion (bottom) mechanisms on the synchronised test rig

The rig was capable of simulating a complete range of static and dynamic loading cycle conditions, with the ability to provide a full range of flexion angles up to a maximum of 90°. A feature of the rig was that the dynamic flexion could be synchronised with the variable vertical and axial loads to represent individual *in vivo* loading conditions.

As with the dynamic loading rig described in section 5.1, the sliding screws were mounted in an adjustable cradle positioned with the axis of rotation coincident with the axis of the lag screw. The cradle was driven by a rack and pinion system coupled to a linear hydraulic actuator, such that the pinion could be rotated through any cycle at predetermined cycle speeds, via the driven rack. This rack and pinion system was developed as a simple, controllable method of providing sufficient torque to rotate the cradle and loaded implant. The fixed vertical load (B_0) was replaced by a variable vertical load, introduced by a cable attached to a ball bearing around the threaded end of the lag screw, the tension provided by a linear hydraulic actuator. A variable parallel load was again applied along the axis of the lag screw (F_s), connected directly to a linear hydraulic actuator which was also situated at the threaded end of the screw. These two actuators could be synchronised electronically to provide the vertical and horizontal components of bodyweight as they altered throughout a movement cycle (Fig 7.2).

The axial and vertical loads applied were recorded by load cells connected to the output shafts of the hydraulic actuators. Data from the transducers was fed directly back into a spreadsheet in a PC, used for control and data acquisition, to compare the output data with the performance data in a control loop. The screw displacement was recorded by a linear displacement transducer parallel to the axial actuator and the angle of flexion and extension was determined by recording the angle of rotation of the cradle and pinion using a rotary displacement transducer. The three hydraulic actuators were controlled using electro-hydraulic servo-valves, with control output voltages fed directly from pre-determined data cycles, stored within the spreadsheet. By using three hydraulic actuators the control system was simplified in terms of the hardware, the electronic control system and the computer software.

7.2 Test Sequences

7.2.1 Verification of Test Rig

An initial set of tests were undertaken to recreate the loading conditions on the dynamic flexion test rig (chapter 5). This was achieved by maintaining a constant vertical component of load (B_0) whilst increasing the axial component (F_s) at a constant rate until sliding occurred. The values for the two components of load were predetermined in the spreadsheet, with the constant value for B_0 calculated from the equation:

$$B_0 = 70 * 9.81 * B_m \sin (159° - ß) / 4$$

Where $B_m = 2.7$ (single leg stance (Kyle *et al.* (1980)))

The parameters of static and dynamic flexion and load application rate were thus investigated on the synchronised loading test rig. Once again, 6 individual tests were completed for each test condition.

Method

Two different loading rates were employed to represent gait speeds. The loading rates were altered by varying the speed at which the data set was output to the servo-valves. Each data set consisted of 1000 data points, covering one cycle. The two output rates used in this test were 150Hz and 600Hz.

Two different flexion cycles were investigated, the conditions of 0° static flexion and 40° dynamic flexion. A data set consisted of the axial sliding force (F_s) increasing from 0N to 1000N over the range of the cycle. For the 0° static flexion, zero was output to the actuator controlling rotation, throughout the cycle (Appendix F: Fig F1). For the 40° dynamic flexion test, the implant was flexed through +40° to -20° for four complete sine wave forms, during one test cycle (Appendix F: Fig F2).

The individual implant parameters were taken from the previous application rate test sequence (section 5.3.3.3), testing a 135° Gamma Nail, with a 95mm screw length and a 135° DHS with a 70mm lag screw length.

Results

The values recorded for the sliding forces within this test sequence were significantly higher than any forces recorded on the dynamic loading test rig under comparable test conditions (Appendix A: Table 43 & Table 44). However the trends exhibited for the different test parameters remained consistent (Fig 7.3).

For the Gamma Nail, under 0° static flexion, a reduction in the sliding force of 34% was recorded between the fast and the slow load application rate. The reduction in force was around 22% for the 40° dynamic flexion condition, between the two application rates. For the slow loading rate, there was a 23% reduction between the 0° static and 40° dynamic flexion conditions. This was reduced to 8% under the fast application rate. These trends were all exhibited in chapter 5 (section 5.3.3.3) when examining the effect of change in the load application rate, with the greatest percentage load reductions induced in comparison to the slow loading condition under 0° static flexion.

The DHS also showed the same pattern of results. Under 0° static flexion the application rate reduction was 25%, reducing to 21% for 40° dynamic flexion. The two flexion conditions varied by 11% under the slow application rate and 9% with the fast rate.

These results indicated that the variation in sliding forces under the different test parameters recorded on the synchronised loading test rig, were comparable with those from the dynamic loading test rig, for the Gamma Nail and the DHS.

7.2.2 *In Vivo* Loading Conditions

A series of everyday clinical loading conditions were represented in simplified loading cycles, to investigate their effect on the sliding performance of the two implants. These consisted of a range of walking cycles, unassisted and assisted, stair ascent and descent, and chair raising.

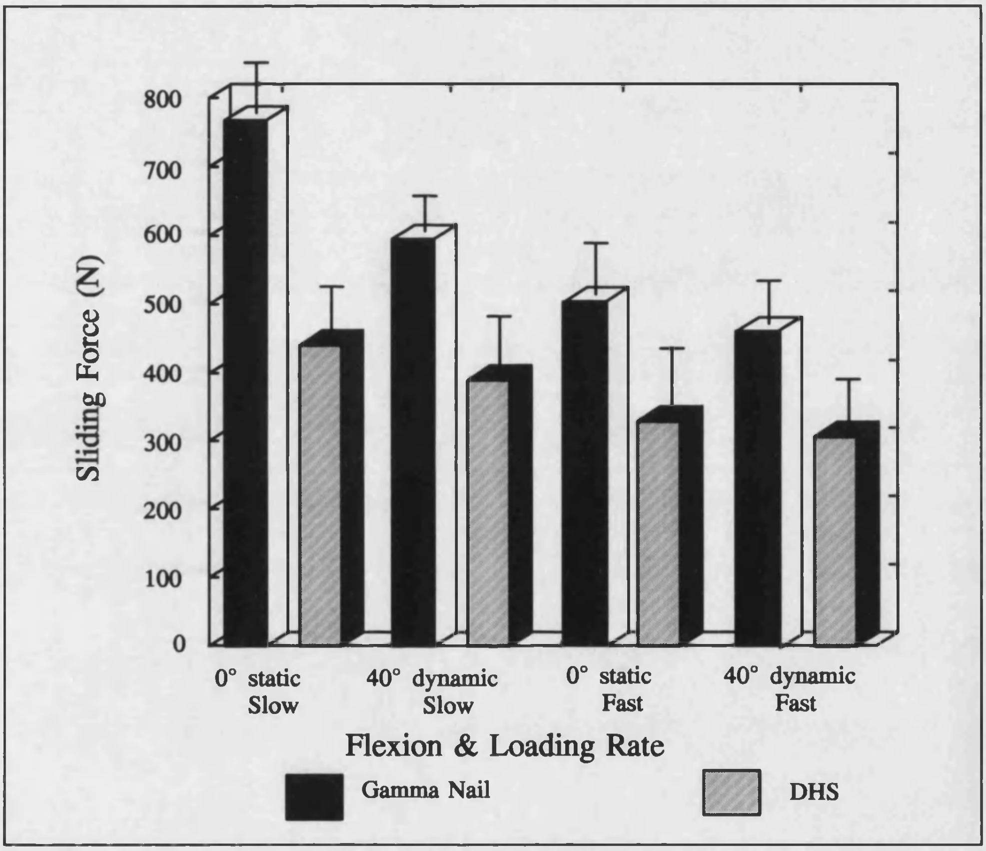

Fig 7.3 - The mean sliding forces with static vertical flexion, from 48 tests.

7.2.2.1 Unassisted Level Walking

A simple dynamic loading pattern was used to represent the walking cycle, consisting of sine wave loading data for the three actuators. The assumption was again made for a 70kg bodyweight, although this was a much more flexible parameter than on the previous test facility.

The axial load (F_s) and the variable vertical load (B_0) were synchronised with each other, to complete two sine cycles in with the respective variations in maximum load.

$$F_s = B'weight * 9.81 * B_m \cos (159° - ß) / 4$$
$$B_0 = B'weight * 9.81 * B_m \sin (159° - ß) / 4$$

Where B_m = the multiple of bodyweight relating to the cycle speed.

The flexion cycle was represented by a single sine cycle. For all three actuator cycles the maximum points occurred at the appropriate percentage of the walking cycle, estimated from a typical walking cycle loading profile (Fig 3.4).

Method

Three different loading rates were employed to represent three unassisted post-operative gaits; fast, intermediate and slow, representing gaits of 0.7m/s, 0.35m/s and 0.175m/s respectively. Assuming one cycle to be equivalent to 1.125m (heel strike to heel strike) (Baker *et al.* (1991)):

0.7 m/s gait	0.6 cycles/sec data output (600Hz)
0.35 m/s gait	0.3 cycles/sec data output (300Hz)
0.175 m/s gait	0.15 cycles/sec data output (150Hz)

A first test series maintained the same multiple of bodyweight (2.7) for the three simulated walking speeds, with a dynamic flexion angle of approximately 30°. This was then repeated with different maximum flexion angles and peak loads determined from the multiples of bodyweight, for the three gait cycles (Appendix F : Fig F3, F4 & F5).

0.7 m/s gait	$B_m = 5.2$	@ 50° flexion
0.35 m/s gait	$B_m = 4.0$	@ 40° flexion
0.175 m/s gait	$B_m = 2.7$	@ 30° flexion

The individual implant parameters were maintained, a 135° Gamma Nail with a 95mm screw length and a 135° DHS with a 70mm lag screw length.

Results

Under simulated walking cycles, no sliding of the lag screw was observed for any of the walking rates with either implant. During the walking profile, the two peak loads occur at around 12% and 48% of the cycle, with a minimum occurring at around 30%. The maximum flexion angle occurs before the heel is put down and the maximum extension after the toe has left the floor (assuming one pace as heel to heel), under conditions of minimum loading. The high loads and maximum flexion conditions therefore never coincide in the walking cycle. With the variable vertical component of load (B_0) in this test sequence, the axial sliding force (F_s) was never great enough to overcome the vertical component of load to initiate sliding of the lag screw.

7.2.2.2 Assisted Level Walking

Assisted level walking was not included as part of the test protocol following the results from the unassisted walking. With the multiples of bodyweight further reduced, it was not felt that sliding would occur under these conditions.

Zimmer	0.175m/s	$B_m = 1$	@ 30° flexion
Crutches	0.175m/s	$B_m = 1.2$	@ 30° flexion
2 canes	0.175m/s	$B_m = 1.6$	@ 30° flexion
1 cane	0.175m/s	$B_m = 1.9$	@ 30° flexion
Normal	0.175m/s	$B_m = 2.7$	@ 30° flexion

7.2.2.3 Stair Ascent and Descent

A simplified loading pattern was used to represent stair ascent and descent (Bergmann *et al* (1990) and McFayden *et al.* (1988)). The assumption was again made for a

70kg bodyweight with the same relationship between the maximum vertical (B_0) and axial (F_s) components of loading

$$F_s = B'weight * 9.81 * B_m \cos (159° - ß) / 4$$
$$B_0 = B'weight * 9.81 * B_m \sin (159° - ß) / 4$$

Where B_m = 3 for stair ascent
B_m = 3.5 for stair descent

The flexion ranged from 60° to 18° for stair ascent and 8° to 48° for stair descent.

Method

The slow loading rate was used for both stair ascent and descent, one cycle being equivalent to one step (Appendix F: Fig F6 & Fig F7). The data was therefore output at 150Hz. Once again, implant parameters remained unchanged, a 135° Gamma Nail with a 95mm lag screw length and a 135° DHS with a 70mm lag screw length.

Results

Under conditions of stair descent, no sliding of the lag screw occurred with either the Gamma Nail or the DHS. When descending, maximum flexion of the hip occurs as the leg is swung from the top step to the lower step. Loading then occurs as the foot is placed on the step, where most of the flexion is accommodated at the knees. Once again therefore, the increased flexion angles and high loading did not coincide, with no initiation of sliding as a result.

With stair ascent, the hip is flexed to place the foot on the upper step and the load gradually increased as the bodyweight is transferred to this leg. Sliding of the lag screw was identified with both implants under this condition (Appendix A: Table 45). Initiation of sliding of the DHS lag screw occurred at an axial sliding force of 323N. From the test rig verification testing (section 7.2.1), the sliding of the DHS lag screw occurred at 393N under slow dynamic flexion conditions and 309N under fast dynamic flexion. The stair ascent result therefore appeared to be representative of sliding of the lag screw under dynamic flexion conditions.

The sliding force required for sliding of the Gamma Nail lag screw was 188N. Verification results for sliding of the Gamma Nail ranged from 598N to 466N (section 7.2.1). The sliding force required in the stair ascent flexion cycle was significantly less than any force previously recorded. The angle of dynamic flexion for stair ascent was a maximum of 60°. This low sliding force was therefore a result of the combination of increased flexion angle and loading cycle pattern.

7.2.2.4 Chair Rising

Once again a simplified loading pattern was used to represent the action of rising from a chair unaided (Rodosky *et al.* (1989)). The assumption was again made for a 70kg bodyweight with the corresponding maximum vertical (B_0) and axial (F_s) components of loading.

$$F_s = \text{B'weight} * 9.81 * B_m \cos (159° - ß) / 4$$
$$B_0 = \text{B'weight} * 9.81 * B_m \sin (159° - ß) / 4$$

Where $B_m = 5.8$ for chair rising

The flexion angle ranged from 90° to 0°.

Method

Once again the slow loading rate was used for chair rising, one complete cycle being sit-to-stand (Appendix F: Fig F8). The implant parameters also remained unchanged, a 135° Gamma Nail with a 95mm lag screw length and a 135° DHS with a 70mm lag screw length.

Results

Sliding of the lag screw occurred with both implants under the chair rising cycle (Appendix A: Table 46). The DHS lag screw required a sliding force of 545N. This force was greater than the force required under 0° static conditions in the verifications tests. This suggests that the high loading conditions represented by the dynamic chair rising cycle were causing excessive damage to the surface of the lag screw as sliding occurred. This could be identified after the testing was completed. The increased friction due to the damaged sliding surface resulted in an increased axial sliding force required to overcome friction. Another contributing factor was that the unsupported DHS lag screw was undergoing elastic deformation as the screw was loaded, tending to bend at the exit of the barrel. This also created resistance to sliding of the lag screw.

Initiation of sliding of the Gamma Nail lag screw occurred at 343N. This result was lower than those recorded for dynamic flexion in the verification tests. The larger diameter lag screw was able to resist bending due to the large vertical component of load, even with a greater lag screw length. There was also less evidence of galling of the lag screw sliding surface, after completion of the tests.

7.3 Discussion

The verification tests on the synchronised loading rig (section 7.2.1) suggested that the results obtained would be comparable with those recorded in chapter 5 on the dynamic loading rig. The earlier rig was simulated by maintaining a constant calculated value of the vertical component of bodyweight (B_0) and gradually increasing the axial force (F_s). The assumptions that sliding would be most likely to occur under conditions of a fast loading rate and increased angles of dynamic flexion were once again supported.

From the clinical data in chapter 6, it was suggested that sliding is unlikely to occur due to walking cycles. From the known post-operative walking ability of a sample group of trial patients, the available axial forces were calculated assuming the multiples of bodyweight relating to the walking ability. In the majority of cases this force was smaller than the forces required to induce sliding, established on the dynamic flexion test rig in chapter 5. This study investigated individual synchronised loading cycles to establish their effect on the sliding performance of the lag screw. Under a simplified walking cycle, neither the DHS or Gamma Nail lag screw was found to slide.

The previous dynamic loading cycles maintained a constant value for the vertical component of load and an increasing horizontal component of load. When the horizontal component had increased enough to overcome the frictional forces induced by the vertical component of load, sliding would occur. This was clearly not a physiological loading condition, where the two components of bodyweight would increase simultaneously. Under synchronised loading, the force required to overcome the frictional resistance increased in line with the vertical and axial force. The conditions under which sliding would occur therefore become more difficult to predict.

Under synchronised walking cycles, the point of maximum load and maximum flexion do not coincide. This variation was enhanced in the simplified walking cycle used in these tests, as the use of a simple sine wave reduced the horizontal component of load to zero between the two maximum peaks. This would not happen in a more realistic physiological loading cycle, where a component of load would remain throughout the entire cycle. However, under both walking cycles, the first peak load occurs as the angle of flexion is rapidly decreasing after the heel is put down. The leg then passes through single leg stance (0°) prior to the second maximum peak, just prior to toe off. The maximum flexion then occurs after toe off as the leg is preparing for its swing phase. The different positions of maximum loading and maximum flexion within the walking cycle, when synchronised, resulted in the lack of sliding under these conditions.

Unlike walking, for conditions of stair ascent and chair rising, the points of maximum flexion and maximum loading were more comparable within the cycle. Sliding of both lag screws occurred with these two loading cycles, as the maximum loads occurred just after the maximum flexion. With stair ascent the flexed leg takes up load as the foot is placed on the upper stair. With chair rising, the flexed leg takes up the load as the bodyweight is raised from the chair. Both of these high flexion cycles resulted in sliding of the lag screw as predicted within the dynamic flexion testing.

To compare the sliding forces recorded for these two test cycles in terms of multiples of bodyweight, a simple calculation could be made from the sliding force as the vertical component of load was synchronised.

For sliding to occur $A_0 = F_s$

$$A_0 = P\cos(159° - ß)$$

Where $P = 70 * 9.81 * B_m/4$

For stair ascent, the calculated multiple of bodyweight suggested the DHS required 2 and the Gamma Nail required multiples of only 1.2. Both of these conditions would be achieved in all post-operative patients when stair climbing, even with a significant degree of assistance. For chair rising the multiples of bodyweight for the DHS and Gamma Nail were calculated to be 3.44 and 2.2 respectively. The physiological maximum values for these two loading conditions in the literature was reported to be 3 and 5.8 times bodyweight. Both these sliding conditions would therefore be achievable in the clinical situation even under assisted movement.

4.4 Closure

These results confirmed the assumption that sliding of the lag screw would be more likely under physiological loading conditions, with slow movement and high flexion. The testing of sliding performance under static loading conditions must therefore be questioned. Under synchronised high flexion conditions the sliding forces required by the Gamma Nail and the DHS were more comparable than under any previous test sequences.

The synchronised test rig was a more complex test facility than the earlier dynamic test rig. By using the computerised control system, the loading and movement cycles could be accurately predetermined. This introduced the flexibility to recreate a number of different loading situations.

Chapter 8

CONCLUSIONS

The overall objective of this study was to develop a test protocol that would enable realistic testing to be undertaken on new and existing sliding hip implants prior to clinical trials or general release. It was postulated that sliding hip screws should be tested under dynamic loading conditions.

The review of clinical literature revealed that failure of sliding hip screws is a recurrent problem, with both the Gamma Nail and the more established Dynamic Hip Screw. The failure modes that were reported were consistent throughout the literature.

The DHS failed due to:	the lag screw cutting out of the femoral head, the cortical screws pulling out of the femur, the lag screw bending, or fatigue failure of the implant itself.
The Gamma Nail failed due to:	the lag screw cutting out of the femoral head, femoral shaft fractures, or fatigue failure of the implant itself.

The cadaveric study (chapter 3) recreated the clinical failure modes within the laboratory environment. The cadaveric femora were statically loaded at a constant rate until failure occurred. The fatigue failure mode of total implant failure, reported for both implants, was therefore not included. The failure loads were recorded for each failure mode. By dividing each femur into three test sections, the individual failure modes were isolated from one another allowing a comparative assessment of the failure loads.

The failure mode of lag screw cut-out within the femoral head was investigated in test sequences using the femoral head in isolation from the femoral shaft. By randomly allocating a DHS or Gamma Nail to the left and right bone within each matched pair, the failure loads between the implants could be directly compared. In the majority of cases the Gamma lag screw resisted failure to higher loads than the DHS. The Gamma Nail consistently failed due to cut-out from the femoral head. The DHS lag screw failed due to cut-out or bending at the point of exit from the barrel. DHS cut-out occurred in femoral heads of inferior bone quality, and lag screw bending occurred in bone that was able to withstand the applied loads beyond the point of implant failure.

A typical patient undergoing internal hip fracture treatment is elderly with poor quality, osteoporotic bone. The failure mode identified within the inferior bone quality therefore represents the common clinical situation more accurately.

The proximal section of each femora.was used to examine the performance of the two implants in unstable intertrochanteric fractures. With the distal test sections, a secondary subtrochanteric fracture was represented within the test configuration. The Gamma Nail was implanted without distal locking screws with the intertrochanteric fractures, which would prevent movement of the intramedullary nail within the femoral canal. The typical Gamma Nail failure modes were a shaft fracture around the bend in the nail or below the lag screw with the intertrochanteric fractures and around the distal locking screw with the subtrochanteric fracture. The DHS failed due to the lag screw bending at the exit of the barrel with the intertrochanteric fracture, and as a result of the cortical bone screws pulling out of the femoral shaft with the subtrochanteric fracture. The corresponding failure loads for the Gamma Nail were consistently higher than the DHS for both fracture configurations. This suggests that the Gamma Nail is a mechanically stronger implant for unstable intertrochanteric or subtrochanteric fractures.

The cadaveric study indicated that the primary clinical failure mode for both implants would be lag screw cut-out from the femoral head. There was no lag screw sliding within the cadaveric study test protocol, which represented the worst case clinical situation of lag screw jamming. This result supports the clinical literature which suggests that under this condition *in vivo*, the most likely failure mode is cut-out of the lag screw. The remaining shaft failure modes would be a result of the load transfer mechanism between the implant and the bone, in cases where lag screw sliding occurs.

From the strain analysis study (chapter 4), the load transfer between the implants and the femoral shaft were examined under identical loading conditions to the intertrochanteric cadaveric study. The DHS transferred the load down the lateral cortex of the femur, creating additional strain around the distal cortical screws. This in turn created instability of the femur due to bending, under the static loading conditions used. The Gamma Nail transferred the load distally down the femoral shaft, with a similar loading pattern to a total joint replacement (Otani *et al.* (1993)). With the larger nail diameter, the additional stiffness of the nail resulted in similar distal loading to an intact femur. However, when the smaller diameter Gamma Nail was tested, the nail moved into three point contact within the femoral canal, again creating high distal loading due to buckling as seen with the DHS.

The DHS involved a relatively simple procedure to implant it into the composite femora used for the strain analysis study. Insertion of the Gamma Nail was a more difficult procedure, complicated by the nature of the composite material. An accurately implanted Gamma Nail would transfer the load across the fracture site and down the femoral canal in a physiological manner. A poorly implanted Gamma Nail, in contrast, would result in three point contact within the femoral shaft, increasing the risk of shaft fracture. The DHS can clinically be regarded as an implant with a reduced risk of failure. The long term prognosis of a laterally loaded femur would not normally be considered a problem, due to the high average age of the patients.

Jamming of the lag screw was the primary concern for the biomechanical studies, identified as the high risk failure mode in the cadaveric study and the reported clinical literature. To analyse the occurrence of lag screw jamming, the antithesis of establishing the optimum condition of screw sliding was investigated. The assumption was made that if the clinical situation deviates from the optimum conditions, jamming would be more likely.

On the dynamic loading rig, the major contributory factors towards lag screw sliding were divided into two groups; those which were predetermined by a patient's physical dimensions and those which were a result of post-operative conditions. The former included the length of the lag screw, the implant angle and the vertical component of load due to bodyweight. The optimum conditions were found to be a high implant angle with a relatively short lag screw length.

The post-operative factors affecting the sliding of the lag screw would be the patient's recovery rate and mobility. From the dynamic flexion study, an increased angle of flexion, dynamically and statically, resulted in a reduction in the force required to induce sliding. Furthermore, an increased rate of load application also resulted in a reduction in the required sliding force. The optimum conditions to induce sliding in a post-operative patient, therefore appear to be a fast long striding walk. Sliding of the implant was also observed under slow and static loading rates, implying that a patient with minimal movement could still induce the implant to slide post-operatively, if the loading through the joint was sufficient.

The relatively small clinical trial suggested that operatively there was no significant difference between the two implants. Surgical preference would therefore play an important role in the selection of the implant design. There was however a 10% reoperation rate with the Gamma Nail. From the data recorded in the clinical trial an indication of the available sliding forces could be calculated. This was completed on a sample group of individual cases with varying post-operative walking mobilities.

From simply considering the walking ability of each patient, the calculated sliding forces would not provide a sufficient force to initiate sliding of the lag screw. This was established by comparing the entire sample group with the forces required from the biomechanical dynamic flexion results. In each of the clinical cases where the lag screw was observed to have moved, the available force was lower than sliding forces from the biomechanical tests. The walking ability of a patient alone is therefore not the only contributory movement under which sliding of the lag screw occurs.

A synchronised loading rig has been developed which has the ability to coordinate the dynamic flexion movement with the application of the load in two directions. This enables more realistic loading situations to be investigated. Walking can be represented by a double peak walking cycle, for a range of peak loads and rates.

There is also the ability to represent synchronised high flexion movement cycles such as stair climbing and chair rising.

The synchronised testing supported the theory that walking was not the most significant contribution to sliding of the lag screw and other movement should be considered. The lag screws did not slide for either implant under simplified walking cycles. A range of walking rates were tested with a corresponding variation in the maximum peak load and the angle of flexion. Maximum loads of up to 5.8 times bodyweight were included in the test protocol under a synchronised walking cycle, with no initiation of sliding. Sliding of the lag screw was recorded for a synchronised stair ascent movement cycle and a synchronised chair rising cycle. The loads required for sliding of the Gamma Nail lag screw under these conditions, were significantly lower in terms the required multiples of bodyweight, than any of the sliding conditions recorded in the dynamic flexion testing. The Gamma Nail sliding forces were of the same order of magnitude, in some cases lower, than those recorded for the DHS. This supports the conclusion that the comparative sliding performance of a range of sliding hip screws cannot be accurately established under static testing.

To compare the clinical performance of sliding hip screws, an understanding of the performance characteristics is essential. Lag screw cut-out is reported as the most significant failure mode in the majority of clinical trials. This is thought to occur in bone of poor quality (osteoporotic) where the lag screw has jammed within the barrel.

Biomechanical testing of any sliding hip screw must therefore consider the sliding ability of the lag screw as part of the protocol. Cadaveric testing was completed under static loading conditions in the majority of studies in the literature. It was also completed under static loading in this study, with the lag screws prevented from sliding to represent the worst clinical situation. However, the isolation of the femoral head from the femoral shaft enabled an investigation of the range of failure modes to be undertaken. Previous studies have only been able to recreate the cut-out failure mode and not the load transfer failure modes as identified with the shaft failures.

Cut-out of the lag screw was found to be partially dependent on the shaft diameter of the lag screw itself and the type of thread. When comparing different implants the superiority incurred by the design of the lag screw should not prevent investigation into the performance of the implant as a whole. By establishing superiority with one failure mode, other failure modes should not be overlooked.

The limitations of strain analysis must be accepted with any biomechanical test protocol. The loading profile shown from this strain analysis indicated that by dividing the femur into two sections, the loading pattern did not represent a complete femur. The strain analysis merely replicated the cadaveric situation, where reactive bending moments at the mounting fixture were recorded. The strain was therefore comparative between the different implants within the study, but could not be compared with any other study or loading situation. To overcome this problem a standard static loading test protocol should be set for cadaveric failure mode tests. This would remove the variation in mounting angles and loading rates between individual studies.

The biomechanical dynamic flexion tests demonstrated that static loading studies cannot accurately recreate the loading conditions experienced by the sliding implant *in vivo*. Sliding of the lag screw was the most significant determinant in the failure rate of sliding hip screws. In cases where the lag screw slides within the barrel, lag screw cut-out was less likely. The overall risk of failure for any sliding hip screw can therefore be estimated from the ability of the lag screw to slide.

Within the development of a suitable biomechanical test protocol to realistically test all sliding hip implants, the sliding ability of the lag screw must be the most significant parameter. To accurately estimate the sliding performance of the lag screws, the optimum conditions of lag screw sliding should be recreated in the test protocol.

Static testing of the sliding ability of the implant was shown to be unrealistic, due to the high sliding forces recorded. This study therefore suggests that to understand the performance of any sliding hip screw, new or old, the implant must undergo realistic dynamic flexion testing.

Sliding of the lag screws does occur in patients where the post-operative mobility is very restricted. The optimum conditions for screw sliding were under conditions of high dynamic flexion. This could involve stair climbing, chair raising or simply moving in bed. The test protocol used to compare implants under realistic conditions, must therefore include a dynamic component of flexion and synchronised loading.

This study has not looked at which is the optimum implant to be used in hip fracture fixation. The focus has been on what is the most appropriate test protocol to compare the performance of different implants. As no current standards exist for the testing of sliding hip screws, there is a need to standardise the range of test methodologies. The most significant failure mode for sliding hip screws is lag screw cut-out of the femoral head, induced by jamming of the lag screw within the barrel of the device. An understanding of the conditions under which sliding occurs has therefore lead to the conclusion that the sliding performance of all hip screws must be investigated under physiological dynamic flexion conditions.

Chapter 9

FURTHER RESEARCH

This study has clearly established that dynamic movement of sliding hip screw devices is one of the major influences on the overall performance of the implant.

A condition highlighted in the cadaveric study was the high forces across the fracture line as a result of the unstable fracture, resulting in screw bending with the DHS lag screw. To understand the loading mechanism, the load transfer across the fracture site should be investigated for a range of fracture configurations. By applying strain gauges to the fracture line and the lag screw itself, the percentage of the total load experienced by the lag screw could be estimated.

The synchronised test rig facility was developed to overcome the drawbacks identified with its predecessor, the dynamic flexion rig. On this latest rig the dynamic flexion movement was synchronised with the load application, allowing a range of different loading conditions to be simulated. This study only examined the effect of simplified movement cycles using the rig. More physiological cycles should be undertaken to achieve a more accurate picture of the optimum conditions for sliding of the lag screw to take place.

From the clinical study, individual patients were highlighted with a range of mobilities, lag screw dimensions and body weights. By reproducing these unique parameters in cyclic tests on the synchronised test rig, the sliding forces obtained would demonstrate the accuracy of the biomechanical representation. A comparison of the sliding forces (F_s) with the maximum sliding forces available in the clinical situation (A_0) would indicate the test cycle accuracy.

A series of tests should be completed on alternative designs of sliding hip screws to achieve a greater database of sliding forces. A typical example would be the Richards Intramedullary Hip Screw (IMHS), a combination of the intramedullary nail system with a longer inserted barrel for the lag screw.

The synchronised test rig clamps the sliding hip screws in individual mounting blocks, attached to the adjustable cradle. This system permits cadaveric and composite femora to be held in the rig. A study should be completed to establish the sliding capability of the lag screw implanted in a femur, where the load carried by the implant is assumed to be 25% of total load applied to the femur, and additional support is provided for the lag screw *in situ*. This would indicate whether the previous isolated implant tests accurately represent of the clinical situation.

The load transfer between the implant and bone was analysed under static loading conditions in the strain study. The load transfer should be analysed under dynamic loading conditions to establish the effect of proximal strain due to sliding of the lag screw.

Chapter 10

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Chapter 11

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Appendix A

TABLES

CADAVERIC STUDY DATA

Number	Femora	Implant location	
		Gamma	DHS
1	P2	R ϕ14	L
2	P3	R ϕ12	L
3	P4	L ϕ14	R
4	P5	R ϕ12	L
5	P6	L ϕ14	R
6	P7	L ϕ14	R
7	P9	L ϕ12	R
8	P12	R ϕ12	L
9	P13	L ϕ12	R
10	P14	L ϕ12	R
11	P15	R ϕ12	L
12	P16	R ϕ12	L

TABLE 1 - Cadaver data showing random distribution of implants

	GAMMA	DHS
SOFT BONE	3634.7N ± 978N	3116.7N ± 494N
HARD BONE	7045.0N ± 488N	4770.0N ± 1278N

TABLE 2 - Mean failure loads for the femoral head tests.

	GAMMA	DHS
SOFT BONE	4066.7N ± 1232N	3277.1N ± 541N
HARD BONE	5652.0N ± 628N	4306.0N ± 677N

TABLE 3 - Mean failure loads for the intertrochanteric fracture tests.

	GAMMA	DHS
SOFT BONE	5725.7N ± 1902N	3225.7N ± 1427N
HARD BONE	5761.2N ± 492N	4660.0N ± 1284N

TABLE 4 - Mean failure loads for the subtrochanteric fracture tests.

FEMORA	BONE GROUP	HEAD TEST		PROX TEST		DIST TEST	
		Gamma	DHS	Gamma	DHS	Gamma	DHS
P2	SOFT	3460	2980	3060	3280	4880	2520
P3	HARD	7960	5180	5700	3880	6220	5280
P4	HARD	2520	3320	4460	4040	5620	4320
P5	SOFT	4540	3600	6120	4500	7740	4020
P6	SOFT	5380	3900	3700	3000	3460	2500
P7	HARD	4980	4000	6160	3420	6040	2300
P9	SOFT	3260	2800	4920	3420	6300	2780
P12	HARD	7000	5200	5760	5020	4860	5640
P13	SOFT	2660	3000	4260	2760	8860	6380
P14	SOFT	3800	2420		3100	5380	2580
P15	SOFT	2340		2340	2880	3460	1800
P16	HARD	8240	4700	6180	5160	6060	5760

TABLE 5 - Failure loads for the individual femora in the cadaveric test sequences.

FEMORA	BONE GROUP	HEAD L_n	L_h	TEST L_m
P2	SOFT	76mm	50mm	34mm
P3	HARD	66mm	38mm	24mm
P4	HARD	81mm	54mm	25mm
P5	SOFT	61mm	42mm	37mm
P6	SOFT	70mm	40mm	27mm
P7	HARD	69mm	43mm	20mm
P9	SOFT	70mm	43mm	24mm
P12	HARD	70mm	44mm	30mm
P13	SOFT	62mm	41mm	18mm
P14	SOFT	70mm	38mm	24mm
P15	SOFT			
P16	HARD	63mm	41mm	30mm

TABLE 6 - Dimensions within the femoral head for the DHS in the femoral head test sequence

STRAIN ANALYSIS STUDY DATA

FEMUR I	Gauge 1	Gauge 2	Gauge 3	Gauge 4	Gauge 5	Gauge 6
Unfractured	-1249.4	-780.5	-110.1	638.6	384.6	-360.9
Unfractured + DHS	-1275.3 (102%)	-643.3 (82%)	-1.4 (1.3%)		207.3 (54%)	-473.1 (131%)
Fractured + DHS	-714.2 (57%)	-393 50%)	550.1 (600%)		-13.2 (3.3%)	-1076.7 (298%)

TABLE 7 - Femur I: mean μstrain at the six gauge positions down the femur

FEMUR II	Gauge 1	Gauge 2	Gauge 3	Gauge 4	Gauge 5	Gauge 6
Unfractured	-1446.1	-836.3	-136.7	742.6	488	-329.9
Unfractured +12mm + DL	-1472.9 (102%)	-658.7 (79%)	-310.9 (227%)	616.4 (83%)	468.7 (96%)	-151.8 (46%)
Unfractured + 12mm	-1407.3 (97%)	-626.1 (75%)	-310.3 (226%)	577.4 (77%)	387.7 (80%)	-137.6 (42%)
Fractured + 12mm + DL		-223.5 (27%)	565.6 (513%)	225.1 (30%)	224.9 (46%)	-892 (270%)
Fractured + 12mm		-290.2 (35%)	613.7 (548%)	233.8 (32%)	202.6 (42%)	-941.4 (285%)

TABLE 8 - Femur II: mean µstrain at the six gauge positions down the femur

FEMUR III	Gauge 1	Gauge 2	Gauge 3	Gauge 4	Gauge 5	Gauge 6
Unfractured	-1132.3	-869.2	-77.8	619.4	460	-334.7
Unfractured +14mm + DL	-1162.2 (103%)	-687.9 (79%)	-295.7 (380%)	384 (62%)	314.3 (68%)	-173.2 (52%)
Unfractured + 14mm	-1160.5 (103%)	-666.2 (77%)	-296.7 (381%)	338 (55%)	313.9 (68%)	-174.8 (52%)
Fractured + 14mm + DL	-716.4 (63%)	-449.7 (52%)	-95.9 (123%)	411.6 (67%)	202.6 (44%)	326.9 (198%)
Fractured + 14mm	704 (62%)	-451.3 (52%)	-88.8 (114%)	395.4 (64%)	182.5 (40%)	-321.5 (196%)

TABLE 9 - Femur III: mean µstrain at the six gauge positions down the femur

BIOMECHANICAL DYNAMIC LOADING STUDY DATA

GAMMA	90mm	95mm	100mm	105mm
0° static	573.0±40.45	581.45±18.15	601.08±41.32	616.75±33.18
40° dynamic	399.4±44.9	419.40±59.0	460.05±27.74	430.88±32.25

TABLE 10 - Gamma Nail: mean sliding forces with variable lag screw length (L_n)

DHS	55mm	60mm	65mm	70mm
0° static	181.0±10.4	195.2±8.94	219.8±26.8	248.1±30.5
30° dynamic	169.9±11.2	173.6±13.4	181.0±7.45	216.1±29.8

TABLE 11 - DHS: mean sliding forces with variable lag screw length (L_n)

GAMMA	0° static	20° dynamic	30° dynamic	40° dynamic
190N	555.8±25.3	470.8±86.4	380.0±37.3	314.4±60.3
155N	484.3±27.6	451.5±65.6	344.9±66.3	283.1±15.7
95N	361.3±23.1	335.3±37.3	285.3±37.3	236.9±29.1
65N	294.3±10.4	275.7±29.8	243.6±17.9	212.3±14.9
30N	171.4±11.2	151.2±17.1	140.1±11.2	113.3±7.45
15N	135.6±2.98	125.2±5.96	102.8±11.2	90.0±7.45

TABLE 12 - Gamma Nail: mean sliding forces with variable static vertical load (B_0)

DHS	30N	65N	95N	155N	190N
0° STATIC	106.5 ±7.45	135.6 ±13.4	172.8 ±21.6	270.4 ±24.6	372.5 ±30.6

TABLE 13 - DHS: mean sliding forces with variable static vertical load (B_0)

DHS	0° static	20° dynamic	30° dynamic	40° dynamic
190N	317.4±61.1	222.0±40.2	208.6±20.9	204.9±33.5
95N	181.0±17.1	130.4±8.19	135.6±12.7	120.7±2.98

TABLE 14 - DHS: mean sliding forces with 35mm barrel length (L_b)

DHS	0° static	20° dynamic	30° dynamic	40° dynamic
190N	316.6±44.7	240.6±19.4	242.9±24.6	238.4±38.7
95N	222.0±45.5	169.9±28.3	184.8±26.1	146.8±33.5

TABLE 15 - DHS: mean sliding forces with 25mm barrel length (L_b)

	0° static	20° dynamic	30° dynamic	40° dynamic
γ 135°	191.5±15.7	161.7±17.1	125.2±11.9	95.4±8.94
DHS 135°	229.5±21.6	199.7±23.1	208.6±43.2	195.9±65.6

TABLE 16 - Gamma Nail and DHS: mean sliding forces for equivalent reaction forces (R_1)

	0° static
γ135°	335.3
DHS 135°	221.3

TABLE 17 - Gamma Nail and DHS: mean sliding forces for equivalent bending

GAMMA	0° static	20° dynamic	30° dynamic	40° dynamic
140°	504.4±23.8	342.7±49.2	263.0±20.9	162.4±12.7
135°	572.2±32.8	455.2±74.5	333.8±15.7	295.8±14.9
130°	608.7±37.3	480.5±81.9	408.3±29.8	327.8±32.0
125°	616.9±19.4	540.9±68.5	488.0±48.4	362.1±37.9

TABLE 18 - Gamma Nail: mean sliding forces with 105mm lag screw length with dynamic flexion

GAMMA	0° static	20° dynamic	30° dynamic	40° dynamic
140°	423.2±5.96	298.0±28.3	251.8±22.4	110.3±5.96
135°	505.1±17.1	397.1±84.2	320.4±52.9	275.7±37.3
130°	598.2±7.45	484.3±81.9	372.5±29.8	310.7±32.0
125°	619.8±18.6	533.4±60.4	415.7±81.9	350.2±35.0

TABLE 19 - Gamma Nail: mean sliding forces with 95mm lag screw length with dynamic flexion

DHS	0° static	20° dynamic	30° dynamic	40° dynamic
150°	130.4±15.7	128.1±11.9	124.4±11.2	122.9±17.1
145°	134.1±8.94	131.1±7.45	126.7±8.20	124.4±11.2
140°	143.8±5.96	136.3±14.2	128.9±14.9	127.4±10.4
135°	157.9±5.96	147.5±11.2	143.8±7.45	142.3±13.4

TABLE 20 - DHS: mean sliding forces with 70mm lag screw length with dynamic flexion

DHS	0° static	20° dynamic	30° dynamic	40° dynamic
150°	117.0±17.1	110.3±11.2	109.5±10.4	102.1±10.4
145°	117.0±3.73	110.3±5.96	108.O±10.4	106.5±21.6
140°	132.6±11.2	119.2±4.47	111.8±8.94	98.3±5.96
135°	147.5±5.96	141.6±18.6	134.1±17.9	136.3±6.71

TABLE 21 - DHS: mean sliding forces with 60mm lag screw length with dynamic flexion

GAMMA	0° static	20° static	30° static	40° static
190N	573.7±33.5	549.8±19.4	540.1±39.5	506.6±27.6
95N	362.8±20.9	344.9±19.4	333.8±22.4	300.3±49.2

TABLE 22 - Gamma Nail: mean sliding forces with 105mm lag screw length with static flexion

GAMMA	0° static	20° static	30° static	40° static
190N	515.5±47.7	493.2±64.1	484.3±20.9	458.2±21.6
95N	342.7±31.3	324.1±20.1	300.3±19.4	294.3±22.4

TABLE 23 - Gamma Nail: mean sliding forces with 95mm lag screw length with static flexion

DHS	0° static	20° static	30° static	40° static
70mm	141.5±8.94	156.5±13.4	169.9±13.4	147.5±14.9
60mm	119.2±13.4	126.7±13.4	130.4±13.4	130.4±11.2

TABLE 24 - DHS: mean sliding forces with 95N static vertical load with static flexion

GAMMA	0° static	20° dynamic	30° dynamic	40° dynamic
FAST	340.18±22.09	323.93±40.47	313.35±20.36	281.20±37.91
INTER.	403.25±21.77	378.48±24.89	346.85±30.03	315.90±24.3
SLOW	452.33±27.91	425.18±68.39	387.85±29.51	344.23±19.49

TABLE 25 - Gamma Nail: mean sliding forces with variable load application rate

DHS	FAST	INTERMED.	SLOW
0° static	161.8±11.21	169.85±11.48	187.35±19.49
40° dynamic	144.9±4.65	151.80±11.69	157.70±15.99

TABLE 26 - DHS: mean sliding forces with variable load application rate

GAMMA	0°	20°	30°	40°
DYNAMIC	481.00±23.65	441.93±53.25	381.09±39.0	294.75±64.75
STATIC	516.70±14.64	500.43±27.93	471.58±19.39	445.87±22.76

TABLE 27 - Gamma Nail: mean sliding forces for known bending moment

DHS	0°	20°	30°	40°
DYNAMIC	172.44±9.14	158.97±11.03	151.60±16.69	142.99±13.88
STATIC	170.71±17.48	156.84±7.37	155.46±15.35	155.17±11.96

TABLE 28 - DHS: mean sliding forces for known bending moment

GAMMA	0° static	20° dynamic	30° dynamic	40° dynamic
WATER	534.2±86.4	499.2±71.5	396.3±61.8	344.2±55.1
LIPID	467.1±27.6	452.2±72.3	397.1±61.8	392.4±55.9

TABLE 29 - Gamma Nail: mean sliding forces with dripped lubrication under dynamic flexion

GAMMA	0° static	20° static	30° static	40° static
LIPID	479.0±37.3	478.3±70.8	452.9±16.4	449.2±73.8

TABLE 30 - Gamma Nail: mean sliding forces with dripped lubrication under static flexion

GAMMA	0° static	20° dynamic	30° Dynamic	40° dynamic
I	508.5±42.5	441.8±60.3	409.8±48.4	437.3±23.1
II	482.0±47.7	435.8±57.4	447.0±34.3	432.1±57.4
III	484.3±36.5	448.5±27.6	433.6±20.9	454.5±42.5

TABLE 31 - Gamma Nail: mean sliding forces with lubrication immersion under dynamic flexion

GAMMA	1	2	3	4	5	6
0° STATIC	543.9 ±73.8	491.7 ±50.7	531.2 ±75.9	-	480.5 ±70.8	545.3 ±67.1
30° DYNAM	350.0 ±64.1	367.3 ±92.4	330.0 ±34.3	363.6 ±98.0	377.7 ±61.8	393.4 ±53.6

TABLE 32 - Gamma Nail: mean sliding forces in repeatability tests

	0° static	20° dynamic	30° dynamic	40° dynamic
γ 135°	4.26±8%	3.6±11%	2.79±10%	2.12±9%
DHS 135°	1.45±9%	1.26±12%	1.32±21%	1.24±34%

TABLE 33 - Gamma Nail and DHS: mean sliding forces for equivalent reaction forces (R_1) in terms of multiple of bodyweight, Ref Table 16

GAMMA	0°	20°	30°	40°
DYNAMIC	3.85±5%	3.54±12%	3.05±10%	2.36±22%
STATIC	4.14±3%	4.01±6%	3.78±4%	3.57±5%

TABLE 34 - Gamma Nail: mean sliding forces for known bending moment in terms of multiples of bodyweight, Ref Table 27

DHS	0°	20°	30°	40°
DYNAMIC	1.09±5%	1.01±7%	0.96±11%	0.90±10%
STATIC	1.08±10%	0.99±5%	0.98±10%	0.98±8%

TABLE 35 - DHS: mean sliding forces for known bending moment in terms of multiples of bodyweight, Ref Table 28

	Stable	Unstable	Subtroch.
Gamma Nail	4	13	2
DHS	10	21	0

TABLE 36 - A breakdown of the fracture configurations for the two implants.

	Gamma Nail	DHS
Sex (F:M)	14:5	22:9
Stable	3:1	7:5
Unstable	10:3	15:6
Subtroch	1:1	
Side (R:L)	5:14	18:13
Stable	2:2	5:5
Unstable	3:10	13:8
Subtroch	0:2	
Age (Years)	80.8	80.4
Stable	87.5	67
Unstable	79.6	83.4
Subtroch	75	
Mental Score (Inc dead)	9.1 (8.7)	9.1 (7.1)
(dead)	3.0	1.7
Stable	8.3	9.2
Unstable	9.0	9.2
Subtroch	7.5	

TABLE 37 - Details of the 50 patients treated in the clinical study.

	Gamma Nail	DHS
Days to Op.	1.8	2.4
Stable	2.8	2
Unstable	1.6	2.8
Subtroch	1.5	
Op Time (mins)	84	68
Stable	79	59
Unstable	105	88
Subtroch	112	
Blood Loss (Mls)	333	430
Stable	310	175
Unstable	450	600

TABLE 38 - Details of the operative times and blood loss for the two implant groups.

	Gamma Nail	DHS
Hospital Stay	18.7	17.7
Stable	16.3	15
Unstable	19.6	18.6
Subtroch	19	
Time to WB	1.6	3.8
Stable	3	2.5
Unstable	1.6	4.9

TABLE 39 - Details of the immediate postoperative performance for the two implant groups.

		PREOP.		POSTOP.	
		Gamma Nail	DHS	Gamma Nail	DHS
Mobility					
Independent	Stable	2	5	0	0
	Unstable	8	6	1	1
	Subtroch	1		0	
Aided	Stable	1	2	3	7
	Unstable	5	7	9	11
	Subtroch	1		2	
Bed Bound	Stable	0	1	0	1
	Unstable	0	2	3	3
	Subtroch	0		0	
Accomodation					
Home	Stable	3	7	3	4
	Unstable	9	9	7	5
	Subtroch	2		1	
Institution	Stable	0	1	0	4
	Unstable	4	6	6	10
	Subtroch	0		1	

TABLE 40 - Details of the six months postoperative performance for the two implant groups.

	Implant	Success/ Failure	Stability	Body-weight	Screw Length	Walking Ability
1	Gamma	Sliding	Unstable	41kg	63	Human assist.
2	Gamma	Sliding	Unstable	78kg	84	2 canes
3	Gamma	Sliding	Unstable	55kg	69	1 cane
4	Gamma	Sliding	Unstable	89kg	72	Unaided
5	Gamma	Cut-out	Unstable	65kg	65	Human assist
6	Gamma	Cut-out	Stable	51kg	60	2 canes
7	DHS	Sliding	Unstable	52kg	32	Human assist.
8	DHS	Sliding	Unstable	57kg	36	2 canes
9	DHS	Sliding	Unstable	43kg	72	1 cane
10	DHS	Sliding	Unstable	60kg	34	Unaided
11	DHS	Cut-out	Unstable	53kg	49	Human assist
12	DHS	Cut-out	Unstable	57kg	68	2 canes

TABLE 41 - A sample group taken from the clinical trial.

	Implant	Body-weight	Walking Ability	P	A_0
1	Gamma	41kg	Human assist.	402N	41N
2	Gamma	78kg	2 canes	1240N	126N
3	Gamma	55kg	1 cane	1025N	104N
4	Gamma	89kg	Unaided	2619N	266N
5	Gamma	65kg	Human assist	638N	65N
6	Gamma	51kg	2 canes	800N	81N
7	DHS	58kg	Human assist.	569N	59N
8	DHS	57kg	2 canes	895N	91N
9	DHS	63kg	1 cane	1174N	119N
10	DHS	60kg	Unaided	1765N	179N
11	DHS	53kg	Human assist	520N	52N
12	DHS	57kg	2 canes	895N	91N

TABLE 42 - The calculated available axial forces for the sample group

BIOMECHANICAL SYNCHRONISED LOADING STUDY DATA

GAMMA	0° static	40° dynamic
FAST	506.1±71.8	466.2±60.3
SLOW	768.7±71.0	506.1±71.8

TABLE 43 - Gamma Nail: mean sliding forces with constant vertical load - verification tests

DHS	0° static	40° dynamic
FAST	331.9±92.1	309.5±69.5
SLOW	442.3±70.9	392.5±78.4

TABLE 44 - DHS: mean sliding forces with constant vertical load - verification tests

	ASCENT	DESCENT
GAMMA	187.7±16.2	-
DHS	322.5±133.6	-

TABLE 45 - Gamma Nail and DHS: mean sliding forces for synchronised stair ascent

	CHAIR RISING
GAMMA	342.5±87.2
DHS	544.4±136.2

TABLE 46 - Gamma Nail and DHS: mean sliding forces for synchronised chair rising

Appendix B

SINGH INDEX

The Singh Index is a system used to classify the level of osteoporosis within a femoral head and neck (Singh *et al.* (1970)). The appearance of the primary and secondary tension and compression trabeculae are visually inspected from X-rays, and a awarded in relation to the degree of visible trabeculae (Fig B1). The grades are distinguished as follows:

Grade 1	Even the principle compressive trabeculae do not stand out in roentgenograms and are markedly reduced in number.
Grade 2	The only prominent trabeculae are the principal compressive group. All the other groups are more or less completely resorbed and become roentgenographically inconspicuous.
Grade 3	There is a break in the continuity of the principal tensile group of trabeculae opposite the greater trochanter. Therefore the tensile trabeculae are clearly seen only in the upper part of the femoral neck, where they are still comparable in density to the principal compressive trabeculae.
Grade 4	The tensile trabeculae are markedly reduced in number. Resorption seems to be proceeding outwards from the centre of the bone. Therefore the principal tensile trabeculae in the outer bone can still be traced in continuity from the lateral cortex to the upper part of the neck of the femur while the secondary compressive trabeculae are completely resorbed.
Grade 5	There is apparent accentuation of the structure of the principal compressive and tensile trabecular groups. The secondary compressive trabeculae are no longer clearly demarcated.

Grade 6 All of the normal groups of trabeculae are visible in the roentgenogram. The compressive and tensile trabeculae cross each other and the upper end of the femur is seen to be completely occupied by cancellous tissue.

Engh *et al.* (1985) utilized a simplified system of categorising the femora using only three grades from the Singh Index in an attempt to overcome inherent problems of variability (Fig B2).

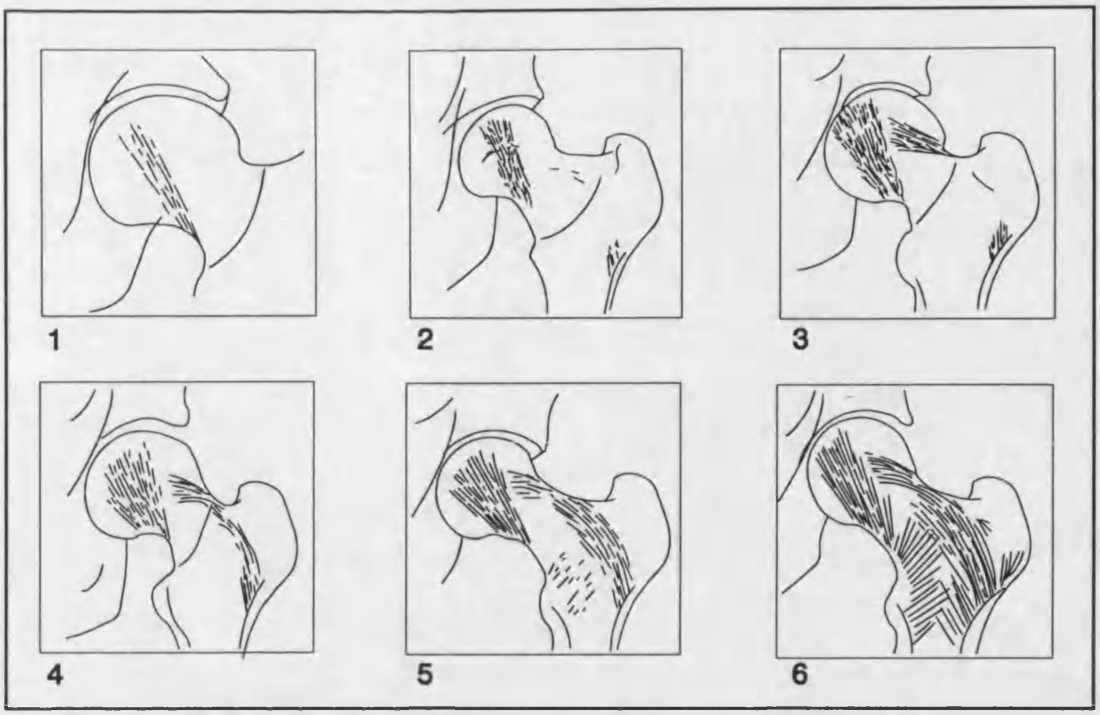


Fig B1 - The six divisions within the Singh Index (Singh *et al.* (1970))

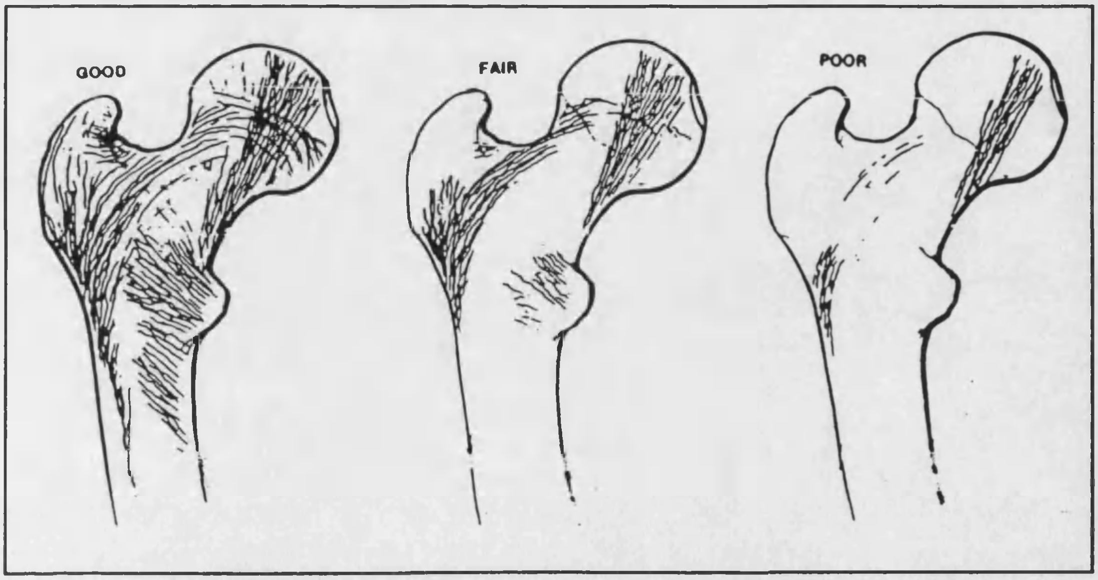


Fig B2 - A simplified Singh Index divided into only three grades (Engh *et al.* (1985)).

Appendix C

STATISTIC ANALYSIS OF CADAVERIC STUDY

The test used was the *t* test, established by W S Gosset in 1908, commonly known as the Student's *t* test. It was designed specifically for small sample groups where it was not possible to confidently state that there is no difference between the mean of the sample being analysed and the mean of the population from which it is taken (Swinscow 1988).

The *t* test returns a probability from a *t* distribution. It determines whether two samples are likely to have come from the same two underlying populations, that have the same mean. By definition, a sample is a random selection of items from a population usually made for evaluating the characteristics of the population. A population is a group of similar items from which a sample is drawn for test purposes, usually assumed to be infinitely large (Lipson *et al.* (1973).

The statistic analysis was undertaken in Excel using the statistical functions package. The analysis was undertaken on paired or 'two sample unequal varience' tests, using a two-tailed distribution. Paired tests were done where a member of sample 1 could be directly paired with sample 2. The two-tailed analysis establishes if one sample is significantly lower OR higher than the other.

1 Paired tests were completed for the two implants in the three test sequences before subdivision into bone quality groups.

	HEAD TEST		INTER. TEST		SUB. TEST	
	Gamma	DHS	Gamma	DHS	Gamma	DHS
P2	3460	2980	3060	3280	4880	2520
P3	7960	5180	5700	3880	6220	5280
P4	2520	3320	4460	4040	5620	4320
P5	4540	3600	6120	4500	7740	4020
P6	5380	3900	3700	3000	3460	2500
P7	4980	4000	6160	3420	6040	2300
P9	3260	2800	4920	3420	6300	2780
P12	7000	5200	5760	5020	4860	5640
P13	2600	3000	4260	2760	8860	6380
P14	3800	2420			5380	2580
P15			2340	2880	3460	1800
P16	8240	4700	6180	5160	6060	5760
P	= 0.013	**(P=0.01)**	=0.005	**(P<0.01)**	=0.0007	**(P<0.001)**

TABLE 47 - Paired *t* tests between implants for complete tests groups.

2 Paired tests were completed on the two bone quality groups in the three test sequences between the two implants.

HARD BONE

HEAD TEST		INTER. TEST		SUB. TEST	
Gamma	DHS	Gamma	DHS	Gamma	DHS
7960	5180	5700	3880	6220	5280
4980	4000	4460	4040	5620	4320
7000	5200	6160	3420	6040	2300
8240	4700	5760	5020	4860	5640
2520	3320	6180	5160	6060	5760
= 0.027	**(P<0.03)**	= 0.032		= 0.216	

TABLE 48 - Paired *t* tests between implants for hard bone quality groups.

SOFT BONE

HEAD TEST		INTER. TEST		SUB. TEST	
Gamma	DHS	Gamma	DHS	Gamma	DHS
3460	2980	3060	3280	4880	2520
4540	3600	6120	4500	7740	4020
5380	3900	3700	3000	3460	2500
3260	2800	4920	3420	6300	2780
2660	3000	4260	2760	8860	6380
3800	2420	2340	2880	5380	2580
				3460	1800
= 0.046	**(P<0.05)**	= 0.107		=0.0005	**(P<0.001)**

TABLE 49 - Paired *t* tests between implants for soft bone quality groups.

3 Two sample unequal varience tests were completed on the two implants in the three test sequences between the bone quality groups.

GAMMA NAIL

HEAD TEST		INTER. TEST		SUB. TEST	
Hard	Soft	Hard	Soft	Hard	Soft
7960	3460	5700	3060	6220	4880
4980	5450	4460	6120	5620	7740
7000	5380	6160	3700	6040	3460
8240	3260	5760	4920	4860	6300
2520	2660	6180	4260	6060	8860
	3800		2340		5380
					3460
= 0.015	**(P<0.02)**	= 0.019	**(P<0.02)**	=0.964	

TABLE 50 - Unequal varience *t* tests between the bone groups for the Gamma Nail.

DHS

HEAD TEST		INTER. TEST		SUB. TEST	
Hard	Soft	Hard	Soft	Hard	Soft
5180	2980	3880	3280	5280	2520
4000	3600	4040	4500	4320	4020
5200	3900	3420	3000	2300	2500
4700	2800	5020	3420	5640	2780
3320	3000	5160	2760	5760	6380
	2420		2880		2580
					1800
= 0.004	**(P<0.005)**	= 0.046	**(P<0.05)**	= 0.12	

TABLE 51 - Unequal varience *t* tests between the bone groups for the DHS

Appendix D

ISOLATED IMPLANT LAG SCREW BENDING TESTS

Lag screw bending was the most common failure mode reported in clinical literature and has been investigated in a number of biomechanical studies. From the cadaveric results, failure due to lag screw bending occurred in specimens of good bone quality. It was unknown under these circumstances what proportion of the applied load was supported by the implant at the barrel, leading to failure. A simple test was undertaken to establish the loads to bending failure for a DHS lag screw and a Gamma Nail lag screw when loaded directly.

Method

Each 135° implant was mounted in the Instron Test machine with the lag screw mounted horizontally. A load was then applied vertically to the end of the lag screw (B_0) with a screw length of 70mm protruding from the barrel (L_n) (Fig D1). The load was applied at a rate of 10mm/min, to repeat the cadaveric loading rate. The loads to failure for the two implants were recorded by a drop in the applied load.

Results

The DHS lag screw bent at a failure load of 1485N.

The Gamma Nail failed due to deformation of the intramedullary nail at the point of lag screw exit from the barrel, at a failure load of 3735N.

For bending at the barrel:

$$\text{Bending Moment} \qquad M = B_0 L_n$$

The bending moment causing implant failure for the DHS was 104Nm.

The bending moment causing implant failure for the Gamma Nail was 262Nm.

Assuming the two implants to be manufactured form similar steel alloys, the variation in load to failure was due to the cross section areas of the two implants, 51mm^2 for the DHS and 113mm^2 for the Gamma lag screw.

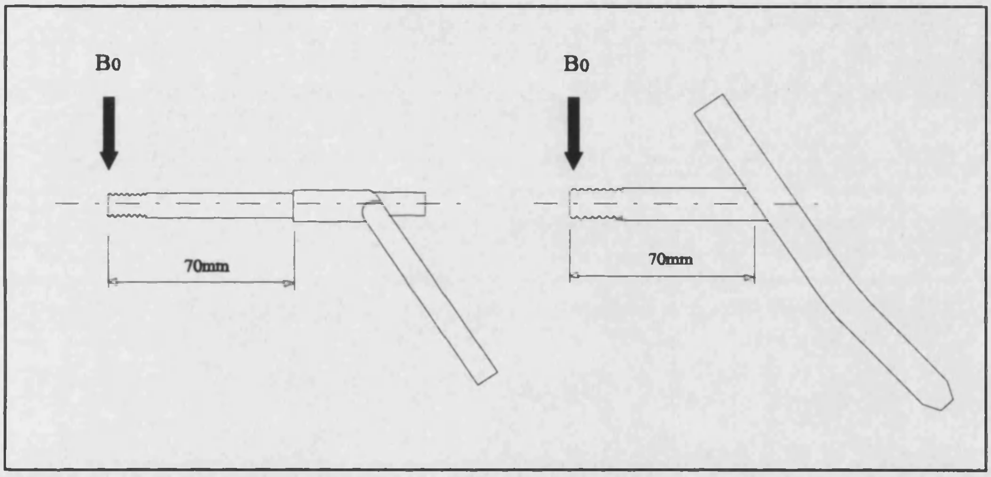


Fig D1 - The loading configuration for the two implants.

Appendix E

CLINICAL TRIAL - PATIENT RECORD FORM

GAMMA LOCKING NAIL VERSUS DYNAMIC HIP SCREW
MULTICENTRE CLINICAL TRIAL
UNIVERSITY OF BATH

Howmedica®

GAMMA LOCKING NAIL VERSUS DYNAMIC HIP SCREW
MULTICENTRE CLINICAL TRIAL
UNIVERSITY OF BATH
REGISTRATION FORM

A1

HOSPITAL NUMBER	☐☐	SEX	☐ MALE
			☐ FEMALE
PATIENT NUMBER	☐☐		
DATE OF ACCIDENT (dd/mm/yy)	☐☐☐	HIP FRACTURED	☐ LEFT
			☐ RIGHT
DATE OF ADMISSION (dd/mm/yy)	☐☐☐		
		CAUSE OF FRACTURE	☐ HOME ACCIDENT
DATE OF OPERATION (dd/mm/yy)	☐☐☐		☐ TRAFFIC ACCIDENT
			☐ WORK ACCIDENT
DATE OF BIRTH (dd/mm/yy)	☐☐☐		☐ SPORTS ACCIDENT
			☐ SPONTANEOUS
WEIGHT (Kg)	☐		☐ SUICIDE ATTEMPT

SURGEON NUMBER	☐	TREATMENT	
		GAMMA NAIL	☐
		DYNAMIC HIP SCREW	☐

GAMMA LOCKING NAIL VERSUS DYNAMIC HIP SCREW
MULTICENTRE CLINICAL TRIAL
UNIVERSITY OF BATH

PRE-OPERATIVE

A1

HOSPITAL NUMBER ☐☐

PATIENT NUMBER ☐☐

DATE OF ACCIDENT (dd/mm/yy) ☐☐☐

DATE OF ADMISSION (dd/mm/yy) ☐☐☐

DATE OF OPERATION (dd/mm/yy) ☐☐☐

DATE OF BIRTH (dd/mm/yy) ☐☐☐

SEX
- ☐ MALE
- ☐ FEMALE

HIP FRACTURED
- ☐ LEFT
- ☐ RIGHT

B1

ACTIVITY SCORE PRIOR TO FRACTURE

KATZ - ADL SCORE ☐

MENTAL SCORE ☐

HAEMOGLOBIN (on admission) ☐ MMO L/L

RESIDENCE BEFORE ADMISSION
- ☐ AT HOME
- ☐ SHELTERED ACCOMODATION
- ☐ OLD PEOPLES HOME
- ☐ NURSING HOME
- ☐ OTHER HOSPITAL

MERLE D'AUBIGNE - ABILITY TO WALK
- ☐ NONE
- ☐ ONLY WITH HUMAN ASSISTANCE
- ☐ ONLY WITH ZIMMER FRAME
- ☐ ONLY WITH CRUTCHES
- ☐ ONLY WITH CANES
- ☐ ONE CANE FOR LESS THAN 1 HOUR
- ☐ LONG TIME WITH CANE
- ☐ WITHOUT CANE WITH SLIGHT LIMP
- ☐ NORMAL

B1

GENERAL COEXISTENT DISEASE
- ☐ NONE
- ☐ DIABETES MELLITUS
- ☐ RESPITORY COMPLAINT
- ☐ ARTERIAL COMPLAINT
- ☐ RENAL INSUFFICIENCY
- ☐ LIVER INSUFFICIENCY
- ☐ MALIGNANCY
- ☐ MENTAL DISORDERS
- ☐ OTHER

BONY COEXISTENT DISEASE
- ☐ NONE
- ☐ PRIMARY BONE TUMOUR
- ☐ BONY METASTESES
- ☐ OSTEITIS DEFORMANS
- ☐ OSTEOGENESIS IMPERFECTA
- ☐ OSTEOMALACIA
- ☐ ARTHROSIS DEFORMANS
- ☐ OTHER

PRE-OPERATIVE HOSPITAL NUMBER [ ][ ] PATIENT NUMBER [ ][ ] PAGE 2

C1 / E1

CLASSIFICATION OF FRACTURE

EVANS

- [ ] TWO FRAGMENTS UNDISPLACED
- [ ] TWO FRAGMENTS DISPLACED
- [ ] THREE FRAGMENTS NO POST LATERAL SUPPORT
- [ ] THREE FRAGMENTS NO MEDIAL SUPPORT
- [ ] FOUR FRAGMENTS (TYPE 3&4)

OTHER

- [ ] SUBTROCHANTERIC
- [ ] LOW SPIRAL SUBTROCHANTERIC

C1

SOFT TISSUE DAMAGE

GUSTILO

- [ ] CLOSED FRACTURE
- [ ] WITH A WOUND LESS THAN 5cm LONG, PERFORATED BY A FRACTURE FRAGMENT
- [ ] WITH A LARGER SKIN LACERATION BUT NO OTHER ESSENTIAL SOFT TISSUE INJURY
- [ ] ADEQUATE COVERAGE OF FRACTURE BY SOFT TISSUE DESPITE EXTENSIVE LACERATIONS
- [ ] EXTENSIVE SOFT TISSUE INJURY WITH PERIOSTEAL STRIPPING AND EXPOSURE OF THE BONE
- [ ] OPEN FRACTURE ASSOCIATED WITH ARTERIAL INJURY REQUIRING REPAIR

E1

SINGH CLASSIFICATION

- [ ] EVEN THE PRINCIPAL COMPRESSIVE TRABECULAE ARE MARKEDLY REDUCED
- [ ] ONLY THE PRINCIPAL COMPRESSIVE TRABECULAE STAND OUT PROMINENTLY
- [ ] BREAK IN THE CONTINUITY OF PRINCIPAL TENSILE TRABECULAE OPPOSITE THE GREATER TROCHANTER
- [ ] PRINCIPAL TENSILE TRABECULAE ARE MARKEDLY REDUCED IN NUMBER BUT CAN STILL BE TRACED
- [ ] THE STRUCTURE OF THE PRINCIPAL TENSILE AND COMPRESSIVE TRABECULAE IS ACCENTUATED
- [ ] NORMAL TRABECULAE GROUPS VISIBLE AND UPPER END COMPLETELY OCCUPIED BY CANCELLOUS BONE

B2

CONCOMITANT THERAPY

- [ ] NONE
- [ ] COUMARIN DERIVATIVES
- [ ] CORTICOSTEROIDS
- [ ] NON-STEROIDAL ANTI-INFLAMMATORIES
- [ ] OTHER ANALGESICS
- [ ] OTHER MEDICATION

ADDITIONAL TRAUMA

- [ ] YES Please give details
- [ ] NO

ANTICOAGULENT PROPHYLAXIS

- [ ] YES Please specify
- [ ] NO

ANTIBIOTIC PROPHYLAXIS

- [ ] YES Please specify
- [ ] NO

POST-OPERATIVE (IMMEDIATE) HOSPITAL NUMBER PATIENT NUMBER PAGE 3

C2

OPERATING SURGEON

- CONSULTANT
- SENIOR REGISTRAR
- REGISTRAR
- SHO
- STAFF GRADE

REDUCTION

- ANATOMIC REDUCTION
- MEDIAL DISPLACEMENT
- VALGUS DISPLACEMENT
- OTHER (Please specify)

TYPE OF ANAESTHESIA

- GENERAL
- SPINAL
- EPIDURAL

C2

ESTIMATED BLOOD LOSS (mls)

ESTIMATED BLOOD GIVEN (units)

OPERATION TIME (minutes)

NUMBER OF DRAINS

C2

GAMMA NAIL

DISTAL DIAMETER	SCREW ANGLE	SCREW LENGTH		DISTAL SCREW
11 mm	125 Degrees	85 mm	105 mm	TOP
12 mm	130 Degrees	90 mm	110 mm	BOTTOM
14 mm	135 Degrees	95 mm	115 mm	
		100 mm	120 mm	

C2

DYNAMIC HIP SCREW

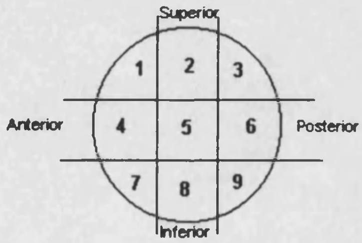
PLATE SIZE	PLATE ANGLE	SCREW LENGTH	
2 Holes	135 Degrees	50 mm	100 mm
4 Holes	140 Degrees	55 mm	105 mm
5 Holes	145 Degrees	60 mm	110 mm
6 Holes	150 Degrees	65 mm	115 mm
8 Holes		70 mm	120 mm
10 Holes	ADDITIONAL SCREWS	75 mm	125 mm
11 Holes		80 mm	130 mm
12 Holes	ADDITIONAL CERCLAGE	85 mm	135 mm
14 Holes	NO	90 mm	140 mm
16 Holes	YES	95 mm	145 mm

C3

SCREW DISTANCE FROM CORTICAL BONE mm

SCREW EXTENSION BEYOND BARREL mm

POSITION OF SCREW IN FEMORAL HEAD (1 TO 9)



POST-OPERATIVE HOSPITAL NUMBER [ ][ ] PATIENT NUMBER [ ][ ] PAGE 4
(AT DISCHARGE)

D1

HAEMOGLOBIN (48 hrs Post-op) [ ] MMO L/L

HAEMOGLOBIN (5 days post-op) [ ] MMO L/L

D1

GENERAL COMPLICATIONS

- [ ] NONE
- [ ] CARDIAC
- [ ] LUNG INFECTION
- [ ] PRESSURE SORE
- [ ] URINARY INFECTION
- [ ] DEEP VEIN THROMBOSIS
- [ ] PULMONARY EMBOLUS
- [ ] OTHER (Please specify) ____________

LOCAL COMPLICATIONS

- [ ] NONE
- [ ] WOUND HAEMATOMA
- [ ] SEROUS EXUDATE
- [ ] PURULENT EXUDATE
- [ ] OSTEITIS
- [ ] OSTEOMYELITIS
- [ ] OTHER (Please specify) ____________

D1

FRACTURE COMPLICATIONS

- [ ] NONE
- [ ] VARUS COLLAPSE - NO SCREW CUT-OUT
- [ ] PERFORATED HEAD - SCREW CUT-OUT
- [ ] SECONDARY FRACTURE - BELOW NAIL
- [ ] SECONDARY FRACTURE - AT DISTAL SCREWS
- [ ] SECONDARY FRACTURE - AROUND PLATE
- [ ] LEG SHORTENING [ ] mm

DEVICE COMPLICATIONS

- [ ] NONE
- [ ] LOOSENING OF THE SCREW
- [ ] NON-GLIDING OF THE SCREW (JAMMING)
- [ ] BENT SCREW
- [ ] BROKEN SCREW
- [ ] PLATE PULL OFF (DHS)
- [ ] MATERIAL BREAKAGE

D1

DATES OF MOBILISATION

OUT OF BED (dd/mm/yy) [ ][ ][ ]

WEIGHT BEARING (dd/mm/yy) [ ]

ESTIMATED WALKING SPEED [ ] m/s

ESTIMATED WALKING GAIT [ ] degrees

MERLE D'AUBIGNE - ABILITY TO WALK

- [ ] NONE
- [ ] ONLY WITH HUMAN ASSISTANCE
- [ ] ONLY WITH ZIMMER FRAME
- [ ] ONLY WITH CRUTCHES
- [ ] ONLY WITH CANES

C4

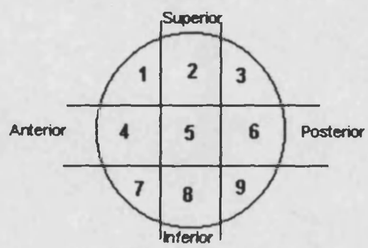
SCREW DISTANCE FROM CORTICAL BONE [ ] mm

SCREW EXTENSION BEYOND BARREL [ ] mm

INTERNAL/EXTERNAL ROTATION (degrees)

AFFECTED SIDE	HEALTHY SIDE
[ ] INTERNAL	[ ] INTERNAL
[ ] EXTERNAL	[ ] EXTERNAL

POSITION OF SCREW IN FEMORAL HEAD (1 TO 9) [ ]



D1

DATE OF FITNESS FOR DISCHARGE (dd/mm/yy) [ ]

DATE OF ACTUAL DISCHARGE (dd/mm/yy) [ ]

RESIDENCE DISCHARGED TO

- [ ] HOME
- [ ] NURSING HOME
- [ ] OLD PEOPLES HOME
- [ ] OTHER HOSPITAL

E2

HOSPITAL NUMBER ☐☐ DATE OF VISIT ☐☐☐

PATIENT NUMBER ☐☐ DATE OF DISCHARGE ☐☐☐

E2

FRACTURE CONSOLIDATED

- ☐ YES
- ☐ NO

RESIDENCE AT ASSESSMENT

- ☐ AT HOME
- ☐ NURSING HOME
- ☐ OLD PEOPLES HOME
- ☐ OTHER HOSPITAL

E2

ACTIVITY SCORE AT 3 MONTH FOLLOW-UP

KATZ - ADL SCORE ☐

MENTAL SCORE ☐

DATES OF MOBILISATION

OUT OF BED (dd/mm/yy) ☐☐☐

WEIGHT BEARING (dd/mm/yy) ☐☐☐

WALKING WITHOUT CANE (dd/mm/yy) ☐☐☐

ESTIMATED WALKING SPEED ☐ m/s

ESTIMATED WALKING GAIT ☐ degrees

MERLE D'AUBIGNE - ABILITY TO WALK

- ☐ NONE
- ☐ ONLY WITH HUMAN ASSISTANCE
- ☐ ONLY WITH ZIMMER FRAME
- ☐ ONLY WITH CRUTCHES
- ☐ ONLY WITH CANES
- ☐ ONE CANE FOR LESS THAN 1 HOUR
- ☐ LONG TIME WITH CANE
- ☐ WITHOUT CANE WITH SLIGHT LIMP
- ☐ NORMAL

E2

MERLE D'AUBIGNE - HIP PAIN

- ☐ PAIN INTENSE AND PERMANENT
- ☐ PAIN SEVERE EVEN AT NIGHT
- ☐ PAIN SEVERE WHEN WALKING
- ☐ PAIN TOLERABLE, LIMITED ACTIVITY
- ☐ PAIN MILD WHEN WALKING, NONE AT REST
- ☐ PAIN IS MILD AND INCONSTANT, NORMAL ACTIVITY
- ☐ NO PAIN

MERLE D'AUBIGNE - HIP MOBILITY

- ☐ ANKYLOSIS WITH BAD HIP POSITION
- ☐ NO MOVEMENT WITH PAIN OR DEFORMITY
- ☐ FLEXION UNDER 40 DEGREES
- ☐ FLEXION BETWEEN 40 & 60 DEGREES
- ☐ FLEXION BETWEEN 60 & 80 DEGREES
- ☐ FLEXION BETWEEN 80 & 90 DEGREES
- ☐ FLEXION GREATER THAN 90 DEGREES

E3

GENERAL COMPLICATIONS

- ☐ NONE
- ☐ URINARY INFECTION
- ☐ CARDIAC
- ☐ DEEP VEIN THROMBOSIS
- ☐ LUNG INFECTION
- ☐ PULMONARY EMBOLUS
- ☐ PRESSURE SORE
- ☐ OTHER (Please specify)

LOCAL COMPLICATIONS

- ☐ NONE
- ☐ OSTEITIS
- ☐ WOUND HAEMATOMA
- ☐ OSTEOMYELITIS
- ☐ SEROUS EXUDATE
- ☐ OTHER (Please specify)
- ☐ PURULENT EXUDATE

3 MONTHS HOSPITAL NUMBER ☐☐ PATIENT NUMBER ☐☐ PAGE 6

E3

FRACTURE COMPLICATIONS

- ☐ NONE
- ☐ VARUS COLLAPSE WITH NO CUT-OUT
- ☐ PERFORATED HEAD - SCREW CUT-OUT
- ☐ SECONDARY FRACTURE - BELOW NAIL
- ☐ SECONDARY FRACTURE - AT DISTAL SCREWS
- ☐ SECONDARY FRACTURE - AROUND PLATE
- ☐ HEAD NECROSIS
- ☐ PSEUDOARTHROSIS
- ☐ LEG SHORTENING ☐ mm

DEVICE COMPLICATIONS

- ☐ NONE
- ☐ LOOSENING OF THE SCREW
- ☐ NON-GLIDING OF THE SCREW-JAMMING
- ☐ BENT SCREW
- ☐ BROKEN SCREW
- ☐ PLATE PULL OFF (DHS)
- ☐ MATERIAL BREAKAGE

E3

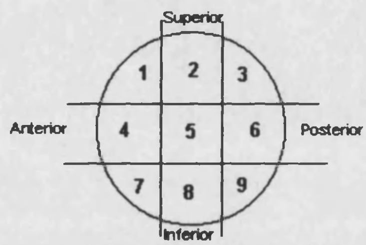
SCREW DISTANCE FROM CORTICAL BONE ☐ mm

SCREW EXTENSION BEYOND BARREL ☐ mm

INTERNAL/EXTERNAL ROTATION (degrees)

AFFECTED SIDE	HEALTHY SIDE
☐ INTERNAL	☐ INTERNAL
☐ EXTERNAL	☐ EXTERNAL

POSITION OF SCREW IN FEMORAL HEAD ☐
(1 to 9)



E3

REMOVAL OF DISTAL SCREW IN GAMMA NAIL

- ☐ YES
- ☐ NO

DATE OF REMOVAL ☐

REMOVAL OF ALL 0STEOSYNTHESIS DEVICE

- ☐ YES
- ☐ NO

DATE OF REMOVAL ☐

E3

READMISSION FOR COMPLICATIONS OF FRACTURE TREATMENT ☐ YES ☐ NO
(If yes give details)

E3

IF NO ASSESSMENT OF PATIENT

- ☐ PATIENT DIED
- ☐ PATIENT UNTRACEABLE
- ☐ OTHER

CAUSE OF DEATH (Please state cause)

DATE OF DEATH ☐

E2

HOSPITAL NUMBER

PATIENT NUMBER

DATE OF VISIT

E2

FRACTURE CONSOLIDATED

- YES
- NO

RESIDENCE AT ASSESSMENT

- AT HOME
- NURSING HOME
- OLD PEOPLES HOME
- OTHER HOSPITAL

E2

ACTIVITY SCORE AT 6 MONTH FOLLOW-UP

KATZ - ADL SCORE

MENTAL SCORE

DATES OF MOBILISATION

OUT OF BED (dd/mm/yy)

FULL WEIGHT BEARING (dd/mm/yy)

WALKING WITHOUT CANE (dd/mm/yy)

ESTIMATED WALKING SPEED m/s

ESTIMATED WALKING GAIT degrees

MERLE D'AUBIGNE - ABILITY TO WALK

- NONE
- ONLY WITH HUMAN ASSISTANCE
- ONLY WITH ZIMMER FRAME
- ONLY WITH CRUTCHES
- ONLY WITH CANES
- ONE CANE FOR LESS THAN 1 HOUR
- LONG TIME WITH CANE
- WITHOUT CANE WITH SLIGHT LIMP
- NORMAL

E2

MERLE D'AUBIGNE - HIP PAIN

- PAIN INTENSE AND PERMANENT
- PAIN SEVERE EVEN AT NIGHT
- PAIN SEVERE WHEN WALKING
- PAIN TOLERABLE, LIMITED ACTIVITY
- PAIN MILD WHEN WALKING, NONE AT REST
- PAIN IS MILD AND INCONSTANT, NORMAL ACTIVITY
- NO PAIN

MERLE D'AUBIGNE - HIP MOBILITY

- ANKYLOSIS WITH BAD HIP POSITION
- NO MOVEMENT WITH PAIN OR DEFORMITY
- FLEXION UNDER 40 DEGREES
- FLEXION BETWEEN 40 & 60 DEGREES
- FLEXION BETWEEN 60 & 80 DEGREES
- FLEXION BETWEEN 80 & 90 DEGREES
- FLEXION GREATER THAN 90 DEGREES

E3

GENERAL COMPLICATIONS

- NONE
- URINARY INFECTION
- CARDIAC
- DEEP VEIN THROMBOSIS
- LUNG INFECTION
- PULMONARY EMBOLUS
- PRESSURE SORE
- OTHER (Please specify)

LOCAL COMPLICATIONS

- NONE
- OSTEITIS
- WOUND HAEMATOMA
- OSTEOMYELITIS
- SEROUS EXUDATE
- OTHER (Please specify)
- PURULENT EXUDATE

E3

FRACTURE COMPLICATIONS

- NONE
- VARUS COLLAPSE WITH NO CUT-OUT
- PERFORATED HEAD - SCREW CUT-OUT
- SECONDARY FRACTURE - BELOW NAIL
- SECONDARY FRACTURE - AT DISTAL SCREWS
- SECONDARY FRACTURE - AROUND PLATE
- HEAD NECROSIS
- PSEUDOARTHROSIS
- LEG SHORTENING mm

DEVICE COMPLICATIONS

- NONE
- LOOSENING OF THE SCREW
- NON-GLIDING OF THE SCREW-JAMMING
- BENT SCREW
- BROKEN SCREW
- PLATE PULL OFF (DHS)
- MATERIAL BREAKAGE

E3

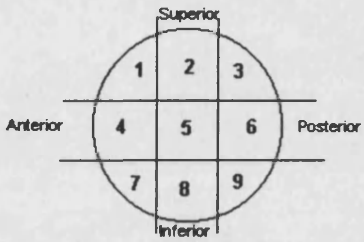
SCREW DISTANCE FROM CORTICAL BONE mm

SCREW EXTENSION BEYOND BARREL mm

INTERNAL/EXTERNAL ROTATION (degrees)

AFFECTED SIDE	HEALTHY SIDE
INTERNAL	INTERNAL
EXTERNAL	EXTERNAL

POSITION OF SCREW IN FEMORAL HEAD
(1 TO 9)



E3

REMOVAL OF DISTAL SCREW IN GAMMA NAIL

- YES
- NO

DATE OF REMOVAL

REMOVAL OF ALL OSTEOSYNTHESIS DEVICE

- YES
- NO

DATE OF REMOVAL

E3

READMISSION FOR COMPLICATIONS OF FRACTURE TREATMENT YES NO
(If yes give details)

E3

IF NO ASSESSMENT OF PATIENT

- PATIENT DIED
- PATIENT UNTRACEABLE
- OTHER

CAUSE OF DEATH (Please state cause)

DATE OF DEATH

INVESTIGATORS STATEMENT
I HAVE READ THIS CASE RECORD FORM IN ITS ENTIRETY AND CONFIRM THAT IT ADEQUATELY REFLECTS THE CLINICAL AND OPERATIVE RECORD OF THIS PATIENT

NAME SIGNATURE DATE

Completion of Case Record Form:

Form

REGISTRATION	The registration form is to be completed on admission of a patient fitting the inclusion criteria. To be completed by the registrar or SHO and sent to the clinical trial monitor. (A1)
PAGE 1	Pre-operative assessment of patient's general condition and any coexistent disease, to be completed by the registrar or SHO. (A1 & B1)
PAGE 2	Pre-operative assessment of injury and therapy, to be completed by the registrar or SHO, the operating surgeon and the clinical trial monitor. (C1, E1 & B2)
PAGE 3	Immediate post-operative record of the operative procedure and implant position, to be completed by the operating surgeon. (C2 & C3)
PAGE 4	Post-operative condition of the patient and the implant position prior to discharge, to be completed by the operating surgeon and the nursing staff or physiotherapist. (D1 & C4)
PAGE 5 - 6	Three month post-operative follow-up, to be recorded by the clinical trial monitor with consultation where necessary. (E2 & E3)
PAGE 7 - 8	Six month post-operative follow-up, to be recorded by the clinical trial monitor with consultation where necessary. (E2 & E3)

Levels of responsibility

Registrar or SHO	**A1**	Registration of patient and record of demographic details.
	B1	Pre-operative assessment of patient recording ability and general condition.
	B2	Pre-operative assessment of therapy.
Operative Surgeon	**C1**	Pre-operative assessment of fracture and tissue damage.
	C2	Operative details, including implant selection.
	C3	Immediate post-operative details of implant position.
	C4	Post-operative details of implant position prior to discharge.
Nursing Staff or Physiotherapist	**D1**	Post operative assessment of patient, recording ability and any complications prior to discharge.
Trial Monitor	**E1**	Classification of osteoporosis using the Singh Index.
	E2	Follow-up assessment of patient, recording ability.
	E3	Follow-up assessment of patient, recording implant position, medical condition and any complications. (With consultation where necessary)

ALL DATA TO BE CHECKED BY CONSULTANT IN CHARGE OF TRIAL AT DISCHARGE

Carbon copies

White	To be retained in the Case Record Form.
Yellow	To be retained by the Clinical Trial Monitor, University of Bath.
Pink	To be retained by Clinical Research Manager, Howmedica International.

Katz - Index of Independence in Activities of Daily Living:

The Index of Independence in Activities of Daily Living is based on an evaluation of the functional independence or dependence of patients in bathing, dressing, going to the toilet, transferring, continence and feeding. Independence means without supervision, direction, or active personal assistance. This is based on actual status and not on ability. A patient who refuses to perform a function is considered as not performing the function, even though he/she is deemed able.

1 = Independent in feeding, continence, transferring, going to the toilet, dressing and bathing.

2 = Independent in all but one of these functions.

3 = Independent in all but bathing and one additional function.

4 = Independent in all but bathing, dressing and one additional function.

5 = Independent in all but bathing, dressing, going to the toilet and one additional function.

6 = Independent in all but bathing, dressing, going to the toilet, transferring and one additional function.

7 = Dependent in all six functions.

8 = Dependent in at least two functions, but not classifiable as 3, 4, 5 or 6.

Evans Fracture Classification:

1 = **Type 1** Undisplaced two fragmentary fracture.

2 = **Type 2** Displaced two fragmentary fracture.

3 = **Type 3** Three fragmentary fracture without posterolateral support due to dislocated greater trochanter fragment.

4 = **Type 4** Three fragmentary fracture without medial support due to dislocated lesser trochanter or femoral arch fragment.

5 = **Type 5** Four fragmentary fracture without medial or posterolateral support; combination of 3 and 4.

Gustilo Soft Tissue Damage Scoring System:

0 = Closed fracture.

1 = **GRADE I** With a wound less than 5cm long from inside out perforated by a fracture fragment.

2 = **GRADE II** With a larger skin laceration but no other essential soft tissue injury.

3 = **GRADE III-A** Adequate coverage of fracture by soft tissue despite extensive lacerations.

4 = **GRADE III-B** Extensive soft tissue injury with periosteal stripping and exposure of the bone.

5 = **GRADE III-C** Open fracture associated with arterial injury requiring repair.

SEPARATOR CARD - PLEASE USE TO PREVENT CARBONING THROUGH TO OTHER SETS

MENTAL TEST

Abbreviated mental test (Quereshi and Hodkinson 1974). The score is the number of questions answered correctly 0 - 10

1.State Age

2.Give the current time to the nearest hour

3.Remember an address and repeat it at the end of the test

4.State the current year

5.Name the institution into which you have been admitted

6.Recognise two persons

7.State date of birth (day and month are sufficient)

8.Give the year of the start of the Second World War

9.Name the present monarch

10.Count backwards from 20 to 1

Appendix F

LOADING PROFILES FOR SYNCHRONISED TEST RIG

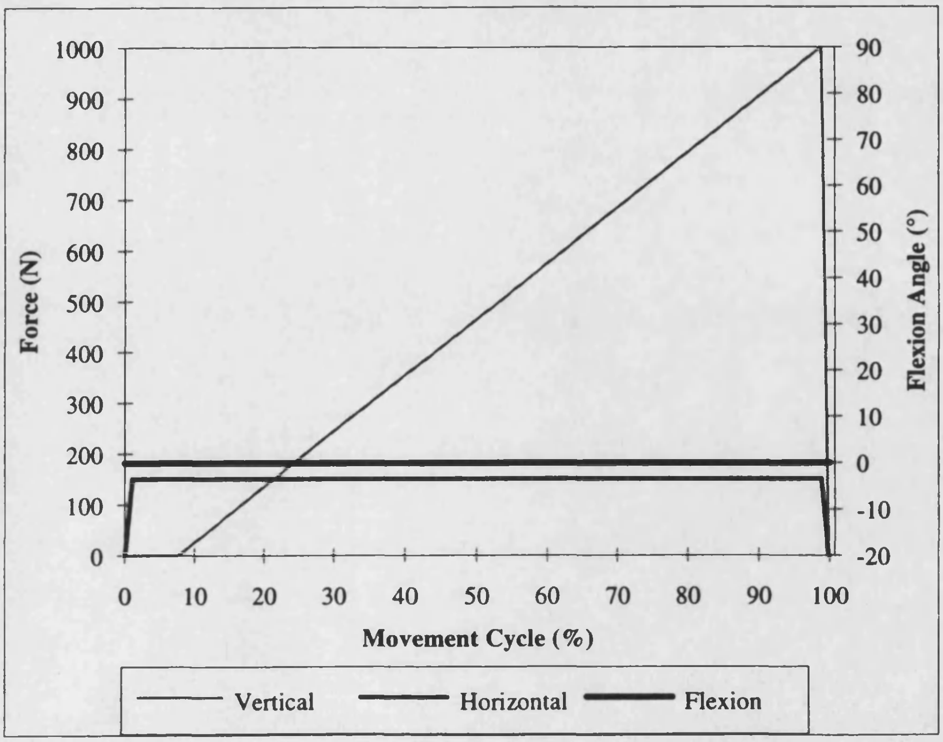


Fig F1 - Static verification test cycle.

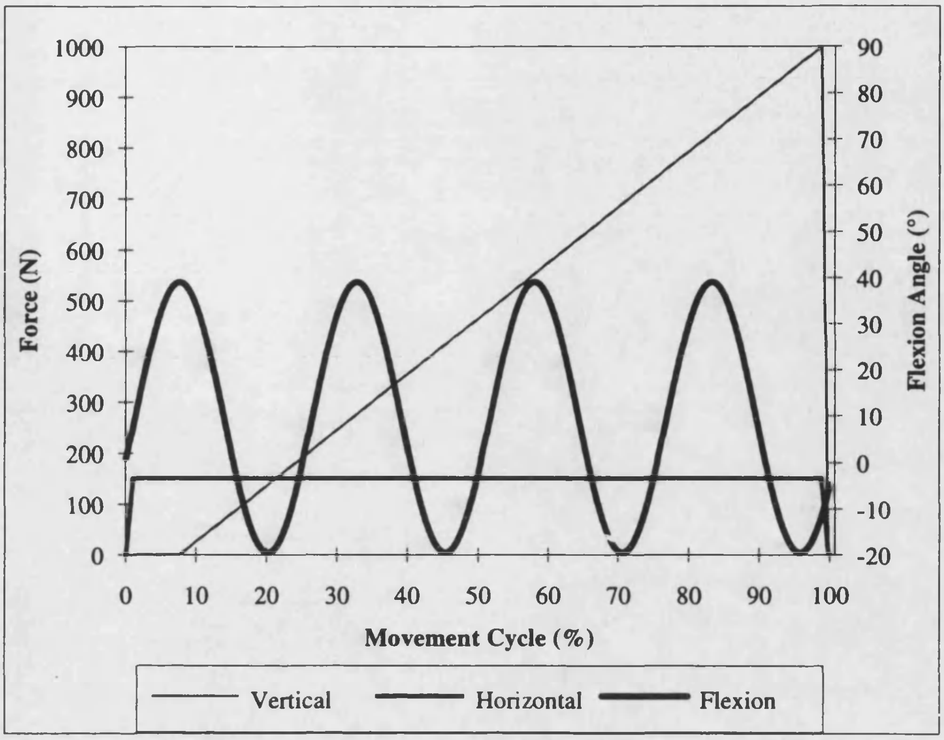


Fig F2 - Dynamic verification test cycle.

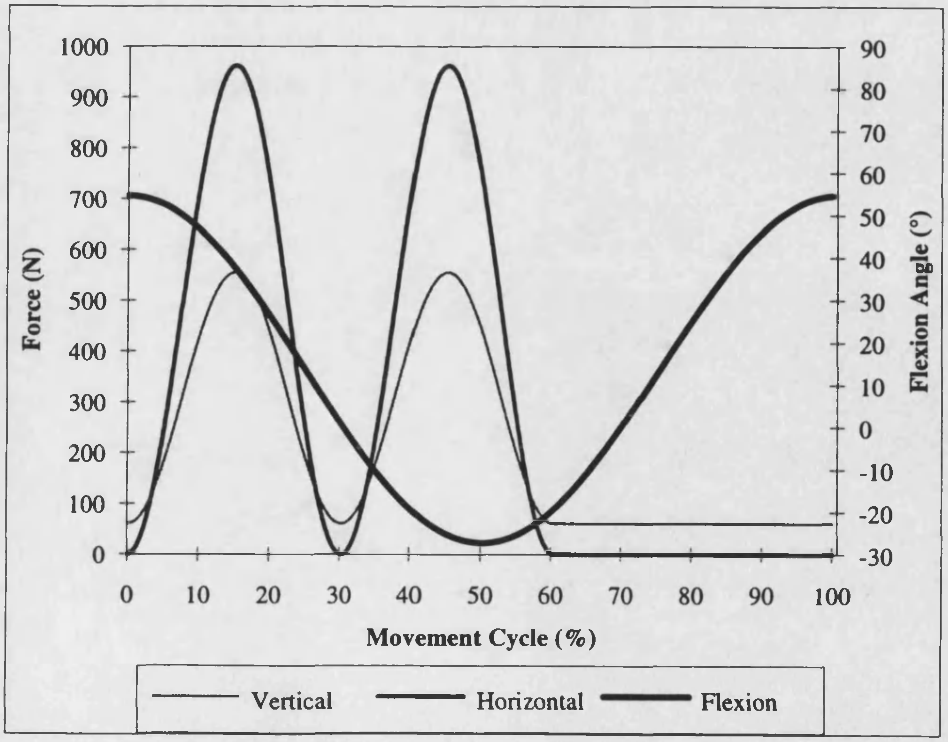


Fig F3 - Fast sine application rate.

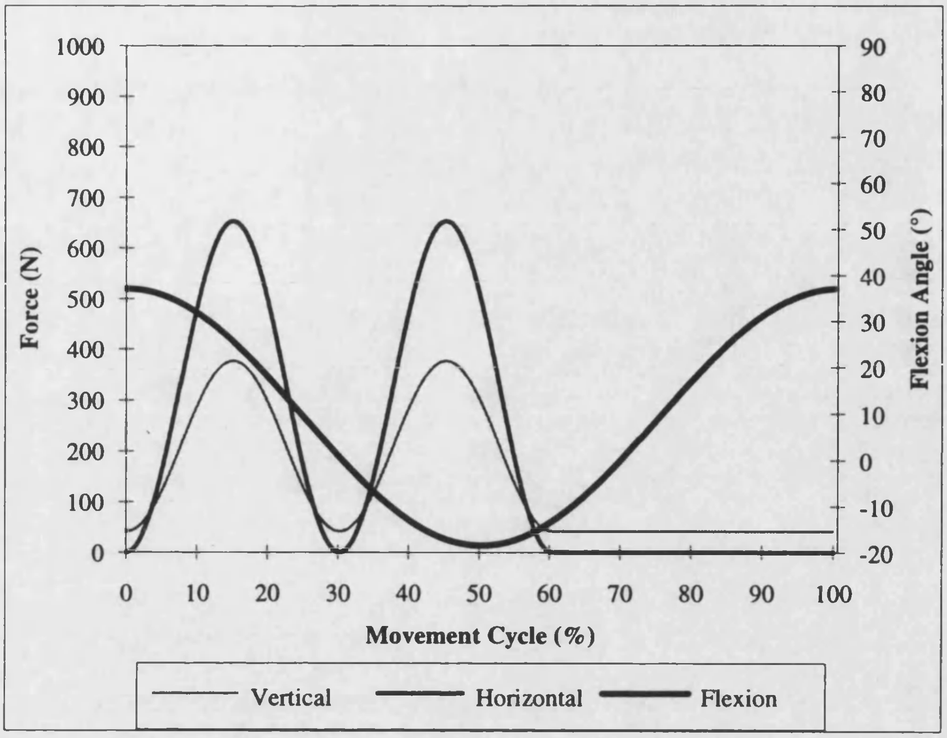


Fig F4 - Medium sine application rate.

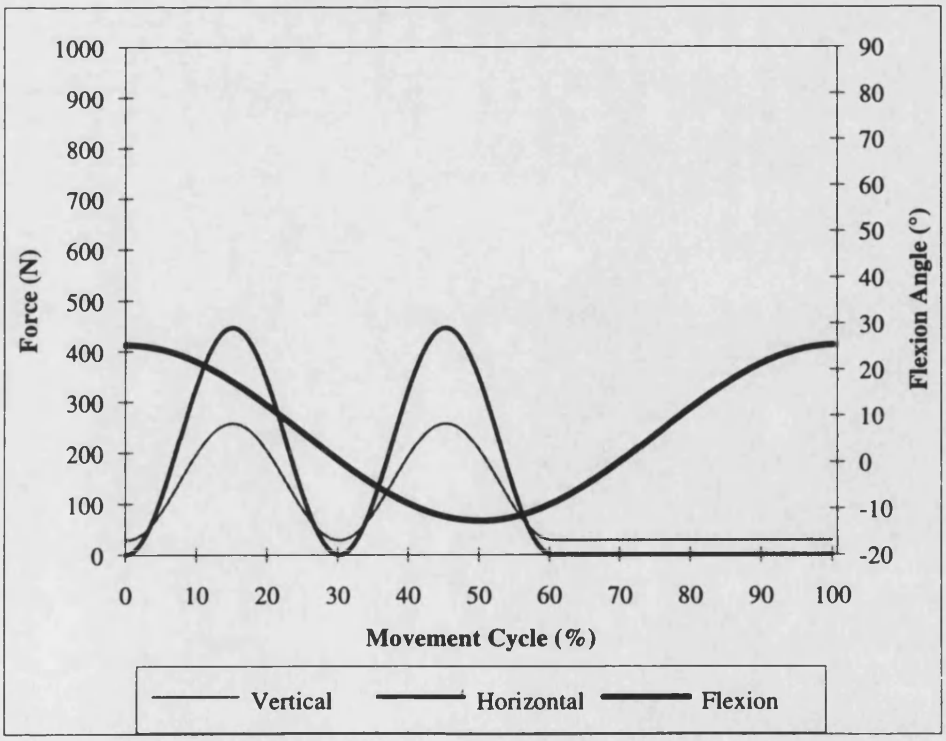


Fig F5 - Slow sine application rate.

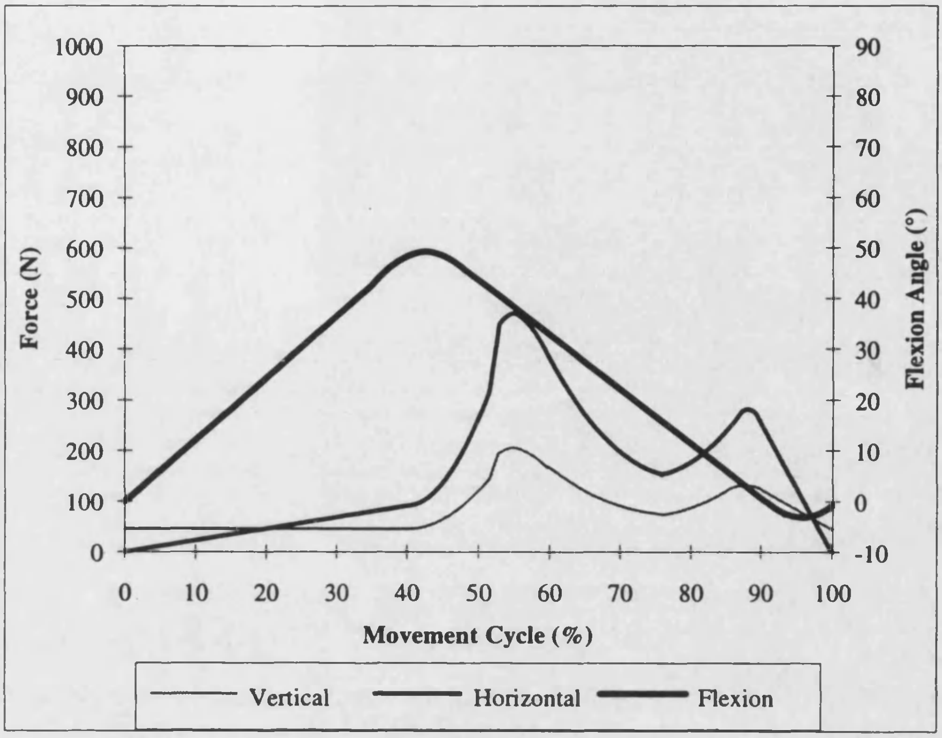


Fig F6 - Stair ascent walking cycle.

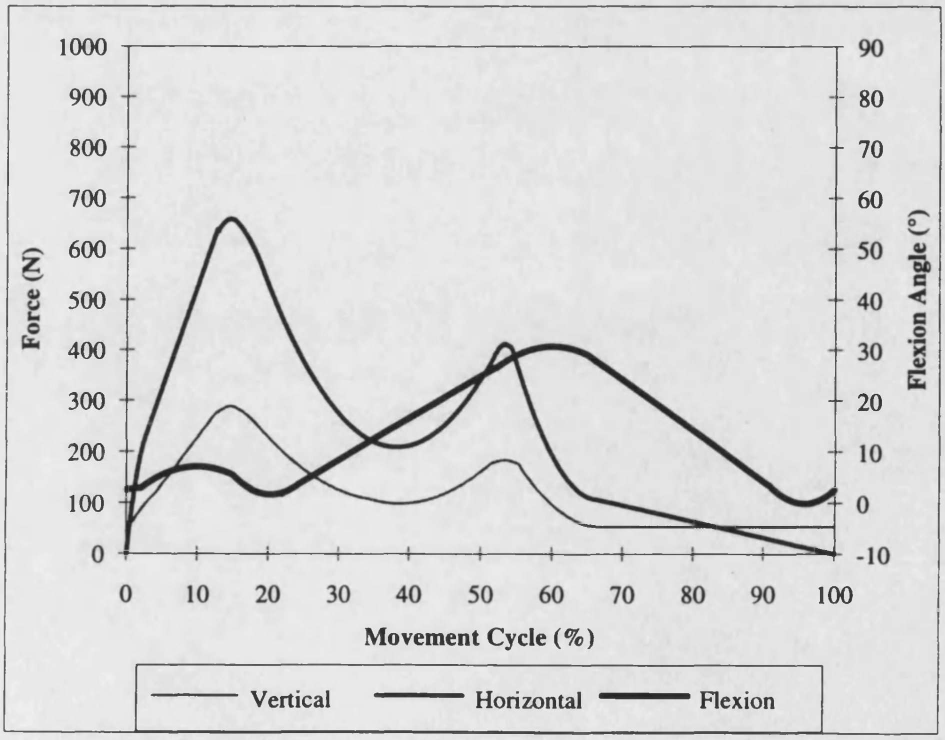


Fig F7 - Stair descent walking cycle.

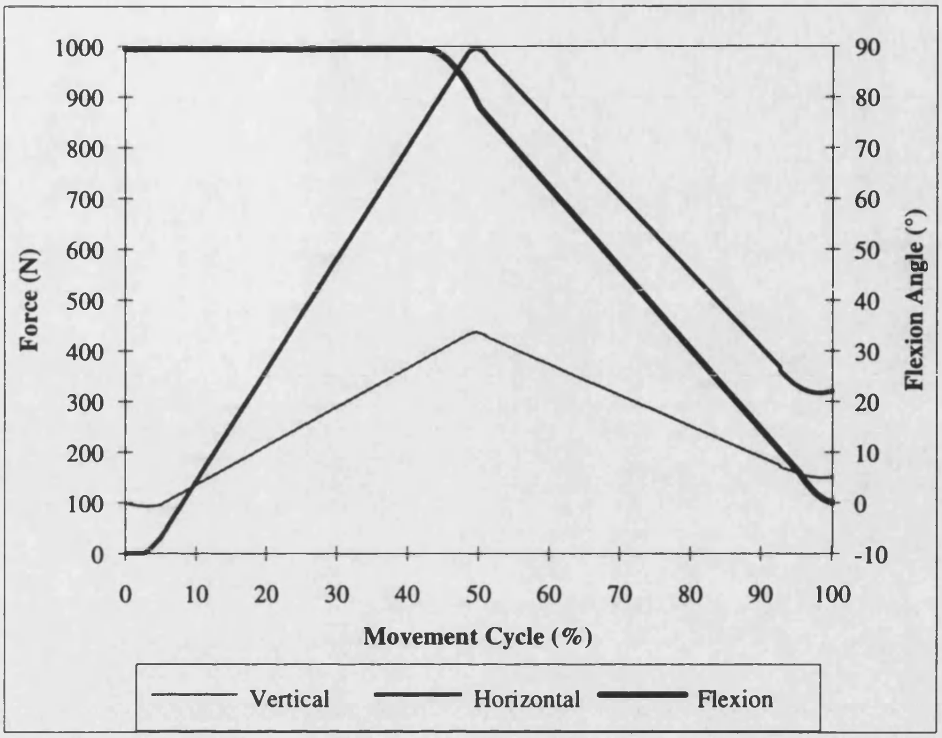


Fig F8 - Sit to stand cycle.

Appendix G

GLOSSARY OF TERMS

Abduction/ Adduction	Movement of the limb away from and towards the midline
Acetabulum	A deep cavity on each side of the hip bone into which the head of the femur fits.
Anatomy	The study of the form and structure of various parts of the human body.
Anteroposterior	From the front to the back, in the coronal plane.
Anteversion	The forward inclination of an organ.
Articular	Pertaining to a joint.
Biomechanics	The mechanics of the body.
Cadaveric	Relating to dead tissue.
Cancellous bone	Lattice like bone.
Cartilage	A dense connective tissue cell matrix capable of withstanding considerable pressure.
Comminuted	A fracture consisting of more than two pieces.
Computerized tomography	Diagnostic radiology using X-ray 'slices', CT scanning
Condyles	The rounded protuberance at the end of some bones that forms an articulation with another bone.
Cortical bone	Hard, compact bone.
Distal	Situated away from the point of origin, eg the part of the limb that is furthest from the body.
Femur	Long bone between the hip and the knee.
Flexion/ Extension	Movement of the limb forward and backwards.
Frontal	Describing the front plane of the body
Greater trochanter	A protuberance near the head of the femur on which the gluteus muscles are inserted.
Hemiarthroplasty	Surgical remodelling of a joint eg replacing the bone end with a prosthesis of metal or plastic.

In vitro	Occurs outside the living body, eg laboratory.
In vivo	Occurs within the living body.
Intertrochanteric	Between the trochanters.
Intramedullary	Within the inner region of any organ or tissue, eg bone.
Lateral	The region that is furthest from the median plane.
Lesser trochanter	A protuberance near the head of the femur, opposite the greater trochanter, on which the psoas muscles are inserted.
Ligament	Fibrous connective tissue linking two bones together at a joint.
Medial	Situated in the central region of the organ, tissue or body.
Median	Situated in the plane that divides the body into right and left halves.
Orthopaedic	The practice of correcting deformities caused by disease of or damage to the bones and joint of the skeleton.
Osteoporosis	Loss of bony tissue resulting in bones that are brittle and liable to fracture.
Osteotomy	A surgical operation to cut a bone in two parts, followed by realignment of the ends to allow healing.
Peritrochanteric	Near or around the trochanters.
Periosteum	Dense connective tissue covering the surface of the bone.
Physiological	In accordance with natural processes of the body.
Proximal	Situated close to the point of origin, eg the part of the limb that is closest to the body.
Radiograph	An X-ray picture.
Roentgenogram	An X-ray picture
Sagittal	Describing the plane down the long axis of the body
Subtrochanteric	Below the trochanters.
Synovial fluid	A thick colourless lubricating fluid that surrounds a joint.
Trabeculae	Fibrous bands of tissue projecting from the outer part of an organ to its interior.
Transverse	Situated at right angles to the long axis of the body.
Valgus	Away from the midline.
Varus	Towards the midline.

Appendix H

PUBLICATIONS

1. **A.W.Miles, R.C.Haynes & R.J.Majkowski** - A static and dynamic evaluation of the sliding characteristics of Gamma Locking Nails.
   Presented at VIII Meeting of the European Society of Biomechanics, Rome. June 1992

2. **A.W.Miles, R.C.Haynes & R.J.Majkowski** - A Biomechanical study of the sliding characteristics of the Gamma Nail under the influence of dynamic loading cycles.
   Journal Paper Submitted to Proc. I. Mech. Eng. Part H 1996

3. **R.C.Haynes, A.W.Miles, R.G.Poll & R.B.Weston** - A cadaveric study of sliding hip screw cut-out failure modes.
   Presented at Second World Congress of Biomechanics, Amsterdam, The Netherlands. July 1994

4. **R.C.Haynes & A.W.Miles** - A biomechanical study of the sliding behaviour of Gamma Nails.
   Presented at Second World Congress of Biomechanics, Amsterdam, The Netherlands. July 1994

5. **R.C.Haynes, A.W.Miles, R.G.Poll & R.B.Weston** - A cadaveric study of sliding hip screw cut-out failure modes.
   Presentation at Annual Meeting of the Orthopaedic Trauma Society, Los Angeles. September 1994

6. **R.C.Haynes & A.W.Miles** - The influence of dynamic loading and movement on the sliding characteristics of the Gamma Nail.
   Presentation at Annual Meeting of the Orthopaedic Trauma Society, Los Angeles. September 1994

7. **R.C.Haynes, A.W.Miles & R.B.Weston** - Investigation into the failure modes of sliding hip screws under static loading: a cadaveric study.
Presentation at European Society of Biomechanics, Leuven, Belgium. August 1996

8. **R.C.Haynes & A.W.Miles** - The effect of loading rate and flexion cycles on the sliding characteristics of an intramedullary sliding hip screw.
Presentation at European Society of Biomechanics, Leuven, Belgium. August 1996